COMMERCIAL PHARMACY PROGRAM POLICY ACTIVITY

Provider Notification

Policies Effective: September 1, 2024 Notification Posted: July 17, 2024

BlueCross BlueShield Minnesota

Contents

NEW POLICIES DEVELOPED

No new policies for September 1, 2024

POLICIES REVISED

• Program Summary: Accrufer (ferric maltol)

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
82300063000120	Accrufer	Ferric Maltol Cap	30 MG	60	Capsules	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when BOTH of the following are met: 1. If the patient has an FDA labeled indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. There is support for using the requested agent for the patient's age for the requested indication **AND** 2. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 6 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Universal QL	**Quantity limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: A. BOTH of the following: 1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **OR** B. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 2. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **Length of Approval:** up to 12 months

• Program Summary: Antiretroviral

Applies to:	☑ Commercial Formularies
Type:	☐ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
12104515200130		Atazanavir Sulfate Cap 150 MG (Base Equiv)	150 MG	30	Tablets	30	DAYS				
12109050001820		Nevirapine Susp 50 MG/5ML	50 MG/5ML	1200	mLs	30	DAYS				
12109050000320		Nevirapine Tab 200 MG	200 MG	60	Tablets	30	DAYS				
12109050007510		Nevirapine Tab ER 24HR 100 MG	100 MG	90	Tablets	30	DAYS				
12109050007520		Nevirapine Tab ER 24HR 400 MG	400 MG	30	Tablets	30	DAYS				
121080700001		stavudine cap	15 MG ; 20 MG ; 30 MG ; 40 MG	60	Capsules	30	DAYS				
12108085000330		Zidovudine Tab 300 MG	300 MG	60	Tablets	30	DAYS				
121099033003	Atripla	efavirenz-emtricitabine-tenofovir df tab	600-200-300 MG	30	Tablets	30	DAYS				
12109903240320	Biktarvy	Bictegravir-Emtricitabine-Tenofovir AF Tab	30-120-15 MG	30	Tablets	30	DAYS				
12109903240330	Biktarvy	Bictegravir-Emtricitabine-Tenofovir AF Tab 50-200-25 MG	50-200-25 MG	30	Tablets	30	DAYS				
12109902470330	Cimduo	Lamivudine-Tenofovir Disoproxil Fumarate Tab 300-300 MG	300-300 MG	30	Tablets	30	DAYS				
121099025003	Combivir	lamivudine-zidovudine tab	150-300 MG	60	Tablets	30	DAYS				
121099034003	Complera	emtricitabine-rilpivirine-tenofovir df tab	200-25-300 MG	30	Tablets	30	DAYS				
121099032703	Delstrigo	doravirine-lamivudine-tenofovir df tab	100-300-300 MG	30	Tablets	30	DAYS				
12109902290310	Descovy	Emtricitabine-Tenofovir Alafenamide Fumarate Tab	120-15 MG	30	Tablets	30	DAYS				
12109902290320	Descovy	Emtricitabine-Tenofovir Alafenamide Fumarate Tab 200-25 MG	200-25 MG	30	Tablets	30	DAYS				
121099022603	Dovato	dolutegravir sodium-lamivudine tab	50-300 MG	30	Tablets	30	DAYS				
121090801003	Edurant	rilpivirine hcl tab	25 MG	30	Tablets	30	DAYS				
121060300001	Emtriva	emtricitabine caps	200 MG	30	Capsules	30	DAYS				
121060300020	Emtriva	emtricitabine soln	10 MG/ML	680	mLs	28	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
121060600020	Epivir	lamivudine oral soln	10 MG/ML	960	mLs	30	DAYS				
12106060000320	Epivir	Lamivudine Tab 150 MG	150 MG	60	Tablets	30	DAYS				
12106060000330	Epivir	Lamivudine Tab 300 MG	300 MG	30	Tablets	30	DAYS				
121099022003	Epzicom	abacavir sulfate-lamivudine tab	600-300 MG	30	Tablets	30	DAYS				
121099022203	Evotaz	atazanavir sulfate-cobicistat tab	300-150 MG	30	Tablets	30	DAYS				
121025300021	Fuzeon	enfuvirtide for inj	90 MG	60	Vials	30	DAYS				
121099042903	Genvoya	elvitegrav-cobic-emtricitab-tenofov af tab	150-150-200-10 MG	30	Tablets	30	DAYS				
12109035000320	Intelence	Etravirine Tab 100 MG	100 MG	60	Tablets	30	DAYS				
12109035000340	Intelence	Etravirine Tab 200 MG	200 MG	60	Tablets	30	DAYS				
12109035000310	Intelence	Etravirine Tab 25 MG	25 MG	120	Tablets	30	DAYS				
12103060100540	Isentress	Raltegravir Potassium Chew Tab 100 MG (Base Equiv)	100 MG	180	Tablets	30	DAYS				
12103060100510	Isentress	Raltegravir Potassium Chew Tab 25 MG (Base Equiv)	25 MG	180	Tablets	30	DAYS				
12103060103020	Isentress	Raltegravir Potassium Packet For Susp 100 MG (Base Equiv)	100 MG	60	Packets	30	DAYS				
12103060100320	Isentress	Raltegravir Potassium Tab 400 MG (Base Equiv)	400 MG	60	Tablets	30	DAYS				
12103060100330	Isentress hd	Raltegravir Potassium Tab 600 MG (Base Equiv)	600 MG	60	Tablets	30	DAYS				
121099022803	Juluca	dolutegravir sodium-rilpivirine hcl tab	50-25 MG	30	Tablets	30	DAYS				
121099025520	Kaletra	lopinavir-ritonavir soln	400-100 MG/5ML	480	mLs	30	DAYS				
12109902550310	Kaletra	Lopinavir-Ritonavir Tab 100-25 MG	100-25 MG	180	Tablets	30	DAYS				
12109902550320	Kaletra	Lopinavir-Ritonavir Tab 200-50 MG	200-50 MG	120	Tablets	30	DAYS				
121045251018	Lexiva	fosamprenavir calcium susp	50 MG/ML	1800	mLs	30	DAYS				
121045251003	Lexiva	fosamprenavir calcium tab	700 MG	120	Tablets	30	DAYS				
121045600020	Norvir	ritonavir oral soln	80 MG/ML	480	mLs	30	DAYS				
121045600030	Norvir	ritonavir powder packet	100 MG	360	Packets	30	DAYS				
121045600003	Norvir	ritonavir tab	100 MG	360	Tablets	30	DAYS				
12109903390320	Odefsey	Emtricitabine-Rilpivirine-Tenofovir AF Tab 200-25-25 MG	200-25-25 MG	30	Tablets	30	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
121090250003	Pifeltro	doravirine tab	100 MG	30	Tablets	30	DAYS				
121099022703	Prezcobix	darunavir-cobicistat tab	800-150 MG	30	Tablets	30	DAYS				
12104520001820	Prezista	Darunavir Oral Susp	100 MG/ML	400	mLs	30	DAYS				
12104520000305	Prezista	Darunavir Tab	75 MG	300	Tablets	30	DAYS				
12104520000310	Prezista	Darunavir Tab	150 MG	180	Tablets	30	DAYS				
12104520000325	Prezista	Darunavir Tab	600 MG	60	Tablets	30	DAYS				
12104520000350	Prezista	Darunavir Tab	800 MG	30	Tablets	30	DAYS				
12108085000110	Retrovir	Zidovudine Cap 100 MG	100 MG	180	Capsules	30	DAYS				
12108085001210	Retrovir	Zidovudine Syrup 10 MG/ML	50 MG/5ML	1920	mLs	30	DAYS				
12104515200140	Reyataz	Atazanavir Sulfate Cap 200 MG (Base Equiv)	200 MG	60	Capsules	30	DAYS				
12104515200150	Reyataz	Atazanavir Sulfate Cap 300 MG (Base Equiv)	300 MG	30	Capsules	30	DAYS				
12104515203020	Reyataz	Atazanavir Sulfate Oral Powder Packet 50 MG (Base Equiv)	50 MG	240	Packets	30	DAYS				
121023304074	Rukobia	fostemsavir tromethamine tab er	600 MG	60	Tablets	30	DAYS				
12102060002020	Selzentry	Maraviroc Oral Soln 20 MG/ML	20 MG/ML	1840	mLs	30	DAYS				
12102060000320	Selzentry	Maraviroc Tab 150 MG	150 ; 150 MG	60	Tablets	30	DAYS				
12102060000305	Selzentry	Maraviroc Tab 25 MG	25 MG	240	Tablets	30	DAYS				
12102060000330	Selzentry	Maraviroc Tab 300 MG	300 ; 300 MG	120	Tablets	30	DAYS				
12102060000310	Selzentry	Maraviroc Tab 75 MG	75 MG	60	Tablets	30	DAYS				
12109904300320	Stribild	Elvitegrav-Cobic-Emtricitab-TenofovDF Tab 150-150-200-300 MG	150-150-200-300 MG	30	Tablets	30	DAYS				
1210155520B720	Sunlenca	Lenacapavir Sodium Tab Therapy Pack	300 MG	4	Tablets	365	DAYS				
1210155520B725	Sunlenca	Lenacapavir Sodium Tab Therapy Pack	300 MG	5	Tablets	365	DAYS				
12109030000140	Sustiva	Efavirenz Cap 200 MG	200 MG	60	Capsules	30	DAYS				
12109030000110	Sustiva	Efavirenz Cap 50 MG	50 MG	90	Capsules	30	DAYS				
12109030000330	Sustiva	Efavirenz Tab 600 MG	600 MG	30	Tablets	30	DAYS				
12109903330340	Symfi	Efavirenz-Lamivudine-Tenofovir DF Tab 600-300-300 MG	600-300-300 MG	30	Tablets	30	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
12109903330330	Symfi lo	Efavirenz-Lamivudine-Tenofovir DF Tab 400-300-300 MG	400-300-300 MG	30	Tablets	30	DAYS				
12109904200320	Symtuza	Darunavir-Cobic-Emtricitab-Tenofov AF Tab 800-150-200-10 MG	800-150-200-10 MG	30	Tablets	30	DAYS				
12103015100305	Tivicay	Dolutegravir Sodium Tab 10 MG (Base Equiv)	10 MG	240	Tablets	30	DAYS				
12103015100310	Tivicay	Dolutegravir Sodium Tab 25 MG (Base Equiv)	25 MG	60	Tablets	30	DAYS				
12103015100320	Tivicay	Dolutegravir Sodium Tab 50 MG (Base Equiv)	50 MG	60	Tablets	30	DAYS				
12103015107320	Tivicay pd	Dolutegravir Sodium Tab for Oral Susp 5 MG (Base Equiv)	5 MG	360	Tablets	30	DAYS				
12109903150320	Triumeq	Abacavir-Dolutegravir-Lamivudine Tab 600-50-300 MG	600-50-300 MG	30	Tablets	30	DAYS				
12109903157320	Triumeq pd	Abacavir-Dolutegravir-Lamivudine Tab for Oral Sus	60-5-30 MG	180	Tablets	30	DAYS				
121099032003	Trizivir	abacavir sulfate-lamivudine-zidovudine tab	300-150-300 MG	60	Tablets	30	DAYS				
121099023003	Truvada	emtricitabine-tenofovir disoproxil fumarate tab	100-150 MG ; 133-200 MG ; 167-250 MG ; 200-300 MG	30	Tablets	30	DAYS				
121095300003	Tybost	cobicistat tab	150 MG	30	Tablets	30	DAYS				
12104545200320	Viracept	Nelfinavir Mesylate Tab 250 MG	250 MG	270	Tablets	30	DAYS				
12104545200340	Viracept	Nelfinavir Mesylate Tab 625 MG	625 MG	120	Tablets	30	DAYS				
121085701029	Viread	tenofovir disoproxil fumarate oral powder	40 MG/GM	240	Grams	30	DAYS				
121085701003	Viread	tenofovir disoproxil fumarate tab	150 MG ; 200 MG ; 250 MG ; 300 MG	30	Tablets	30	DAYS				
12105005102020	Ziagen	Abacavir Sulfate Soln 20 MG/ML (Base Equiv)	20 MG/ML	960	mLs	30	DAYS				
121050051003	Ziagen	abacavir sulfate tab	300 MG	60	Tablets	30	DAYS				

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity limit for the Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: A. BOTH of the following:

	1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **OR** B. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 2. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** C. BOTH of the following: 1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **Length of Approval:** up to 12 months

• Program Summary: Bempedoic Acid

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
39380020000320	Nexletol	Bempedoic Acid Tab 180 MG	180 MG	30	Tablets	30	DAYS				
39991002200320	Nexlizet	Bempedoic Acid-Ezetimibe Tab 180-10 MG	180-10 MG	30	Tablets	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
PA	**Initial Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. BOTH of the following: 1. ONE of the following: A. The patient has a diagnosis of primary hyperlipidemia (including heterozygous familial hypercholesterolemia [HeFH]) **OR** B. The patient is using the requested agent to reduce the risk of myocardial infarction and coronary revascularization AND ONE of the following: 1. The patient has established cardiovascular disease (CVD) **OR** 2. The patient has a high risk for a CVD event **AND** 2. ONE of the following: A. The patient has tried and had an inadequate response to at least ONE statin **OR** B. The patient has an intolerance or hypersensitivity to ALL statin therapies **OR** C. The patient has an FDA labeled contraindication to ALL statin therapies **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND**

	2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that statins cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** B. The patient has another FDA labeled indication for the requested agent and route of administration **OR** C. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND** 2. If the patient has an FDA labeled indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. There is support for using the requested agent for the patient's age for the requested indication **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS or DrugDex 1 or 2a level of evidence **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following criteria are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS or DrugDex 1 or 2a level of evidence **Length of approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity limit for the Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: A. BOTH of the following: 1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **OR** B. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND**

	2. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** C. BOTH of the following: 1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **Length of Approval:** up to 12 months

• Program Summary: Cibinqo (abrocitinib)

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
90272005000320	Cibinqo	Abrocitinib Tab	50 MG	30	Tablets	30	DAYS			09-01-2022	
90272005000325	Cibinqo	Abrocitinib Tab	100 MG	30	Tablets	30	DAYS			09-01-2022	
90272005000330	Cibinqo	Abrocitinib Tab	200 MG	30	Tablets	30	DAYS			09-01-2022	

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The requested agent is eligible for continuation of therapy AND ONE of the following: **Agents Eligible for Continuation of Therapy** All target agents are eligible for continuation of therapy 1. The patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR** 2. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR** B. BOTH of the following: 1. ONE of the following: A. The patient has a diagnosis of moderate-to-severe atopic dermatitis (AD) AND ALL of the following: 1. ONE of the following: A. The patient has at least 10% body surface area involvement **OR** B. The patient has involvement of body sites that are difficult to treat with prolonged topical corticosteroid therapy (e.g., hands, feet, face, neck, scalp, genitals/groin, skin folds) **OR** C. The patient has an Eczema Area and Severity Index (EASI) score greater than or equal to 16 **OR** D. The patient has an Investigator Global Assessment (IGA) score greater than or equal to 3 **AND** 2. ONE of the following:

A. The patient has tried and had an inadequate response to at least a medium-potency topical corticosteroid used in the treatment of AD **OR**
B. The patient has an intolerance or hypersensitivity to at least a medium-potency topical corticosteroid used in the treatment of AD **OR**
C. The patient has an FDA labeled contraindication to ALL medium-, high-, and super-potency topical corticosteroids used in the treatment of AD **OR**
D. The patient is currently being treated with the requested agent as indicated by ALL of the following:
    1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
    2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on the requested agent **AND**
    3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
E. The prescriber has provided documentation that ALL medium-, high-, and super-potency topical corticosteroids used in the treatment of AD cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**

3. ONE of the following:
A. The patient has tried and had an inadequate response to a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) used in the treatment of AD **OR**
B. The patient has an intolerance or hypersensitivity to a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) used in the treatment of AD **OR**
C. The patient has an FDA labeled contraindication to ALL topical calcineurin inhibitors used in the treatment of AD **OR**
D. The patient is currently being treated with the requested agent as indicated by ALL of the following:
    1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
    2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on the requested agent **AND**
    3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
E. The prescriber has provided documentation that ALL topical calcineurin inhibitors used in the treatment of AD cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**

4. The prescriber has documented the patient's baseline (prior to therapy with the requested agent) pruritus and other symptom severity (e.g., erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification) **OR**

B. The patient has another FDA labeled indication for the requested agent and route of administration **AND**

2. If the patient has an FDA labeled indication, then ONE of the following:

A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**
B. There is support for using the requested agent for the patient's age for the requested indication **OR**

C. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND**

2. If the patient has a diagnosis of moderate-to-severe atopic dermatitis (AD), then BOTH of the following:
   A. The patient is currently treated with topical emollients and practicing good skin care **AND**
   B. The patient will continue the use of topical emollients and good skin care practices in combination with the requested agent **AND**
3. The patient has been tested for latent tuberculosis (TB) AND if positive the patient has begun therapy for latent TB **AND**
4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist, allergist, immunologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**
5. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table):
   A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR**
   B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following:
      1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND**
      2. There is support for the use of combination therapy (submitted copy of clinical trials, phase III studies, guidelines required) **AND**
6. The patient does NOT have any FDA labeled contraindications to the requested agent

Compendia Allowed: AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use

Length of Approval: 6 months

NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

Renewal Evaluation

Target Agent(s) will be approved when ALL of the following are met:

1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND**
2. ONE of the following:
   A. The patient has a diagnosis of moderate-to-severe atopic dermatitis AND BOTH of the following:
      1. The patient has had a reduction or stabilization from baseline (prior to therapy with the requested agent) of ONE of the following:
         A. Affected body surface area **OR**
         B. Flares **OR**
         C. Pruritus, erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification **OR**
         D. A decrease in the Eczema Area and Severity Index (EASI) score **OR**
         E. A decrease in the Investigator Global Assessment (IGA) score **AND**
      2. The patient will continue standard maintenance therapies (e.g., topical emollients, good skin care practices) in combination with the requested agent **OR**
   B. The patient has a diagnosis other than moderate-to-severe atopic dermatitis AND has had clinical benefit with the requested agent **AND**
3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist, allergist, immunologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**

	4. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** 2. There is support for the use of combination therapy (submitted copy of clinical trials, phase III studies, guidelines required) **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed**: AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **Length of Approval**: 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Universal QL	**Quantity limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: A. BOTH of the following: 1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **OR** B. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 2. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **Length of Approval:** up to 12 months

CONTRAINDICATION AGENTS

Contraindicated as Concomitant Therapy
Agents NOT to be used Concomitantly
Abrilada (adalimumab-afzb)
Actemra (tocilizumab)
Adalimumab
Adbry (tralokinumab-ldrm)
Amjevita (adalimumab-atto)
Arcalyst (rilonacept)
Avsola (infliximab-axxq)
Benlysta (belimumab)
Bimzelx (bimekizumab-bkzx)
Cibinqo (abrocitinib)
Cimzia (certolizumab)
Cinqair (reslizumab)
Cosentyx (secukinumab)
Cyltezo (adalimumab-adbm)
Dupixent (dupilumab)

Contraindicated as Concomitant Therapy
Enbrel (etanercept)
Entyvio (vedolizumab)
Fasenra (benralizumab)
Hadlima (adalimumab-bwwd)
Hulio (adalimumab-fkjp)
Humira (adalimumab)
Hyrimoz (adalimumab-adaz)
Idacio (adalimumab-aacf)
Ilaris (canakinumab)
Ilumya (tildrakizumab-asmn)
Inflectra (infliximab-dyyb)
Infliximab
Kevzara (sarilumab)
Kineret (anakinra)
Litfulo (ritlecitinib)
Nucala (mepolizumab)
Olumiant (baricitinib)
Omvoh (mirikizumab-mrkz)
Opzelura (ruxolitinib)
Orencia (abatacept)
Otezla (apremilast)
Remicade (infliximab)
Renflexis (infliximab-abda)
Riabni (rituximab-arrx)
Rinvoq (upadacitinib)
Rituxan (rituximab)
Rituxan Hycela (rituximab/hyaluronidase human)
Ruxience (rituximab-pvvr)
Siliq (brodalumab)
Simlandi (adalimumab-ryvk)
Simponi (golimumab)
Simponi ARIA (golimumab)
Skyrizi (risankizumab-rzaa)
Sotyktu (deucravacitinib)
Spevigo (spesolimab-sbzo)
Stelara (ustekinumab)
Taltz (ixekizumab)
Tezspire (tezepelumab-ekko)
Tofidence (tocilizumab-bavi)
Tremfya (guselkumab)
Truxima (rituximab-abbs)
Tyenne (tocilizumab-aazg)
Tysabri (natalizumab)
Velsipity (etrasimod)
Wezlana (ustekinumab-auub)
Xeljanz (tofacitinib)
Xeljanz XR (tofacitinib extended release)
Xolair (omalizumab)
Yuflyma (adalimumab-aaty)
Yusimry (adalimumab-aqvh)
Zeposia (ozanimod)
Zymfentra (infliximab-dyyb)

• Program Summary: Coagulation Factor VIIa

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

QUANTITY LIMIT INFORMATION

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Additional QL Information	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
85100026202117	Novoseven rt	Coagulation Factor VIIa (Recomb) For Inj 1 MG (1000 MCG)	1 MG	Dependent on patient weight and number of doses			
85100026202126	Novoseven rt	Coagulation Factor VIIa (Recomb) For Inj 2 MG (2000 MCG)	2 MG	Dependent on patient weight and number of doses			
85100026202145	Novoseven rt	Coagulation Factor VIIa (Recomb) For Inj 5 MG (5000 MCG)	5 MG	Dependent on patient weight and number of doses			
85100026202160	Novoseven rt	Coagulation Factor VIIa (Recomb) For Inj 8 MG (8000 MCG)	8 MG	Dependent on patient weight and number of doses			
85100026402117	Sevenfact	Coagulation Factor VIIa (Recom)-jncw For Inj	1 MG	Dependent on patient weight and number of doses			
85100026402145	Sevenfact	Coagulation Factor VIIa (Recom)-jncw For Inj	5 MG	Dependent on patient weight and number of doses			

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
NovoSeven RT	**NovoSeven RT** will be approved when ALL of the following are met: 1. ONE of the following: A. BOTH of the following: 1. ONE of the following A. The patient has a diagnosis of hemophilia A AND BOTH of the following: 1. The patient has inhibitors to Factor VIII **AND** 2. The requested agent is being used for ONE of the following: A. On-demand use for bleeds AND ONE of the following: 1. The prescriber communicated with the patient (via any means) regarding the frequency and severity of the patient's bleeds and has verified that the patient does not have greater than 5 on-demand doses on hand **OR** 2. There is support for the patient having more than 5 on-demand doses on hand (supportive reasoning required) **OR** B. Prophylaxis AND ALL of the following: 1. ONE of the following: A. The patient has tried and had an inadequate response to Immune Tolerance Induction (ITI) [Immune Tolerance Therapy (ITT)] **OR** B. The patient has an inhibitor level greater than or equal to 200 BU (lab records required) **OR** C. The patient is not a candidate for ITI **AND** 2. The patient will NOT be using the requested agent in combination with Hemlibra **AND** 3. The patient will NOT be using the requested agent in combination with Feiba [activated prothrombin complex (aPCC)] used for prophylaxis (on-demand use of aPCC is acceptable) **OR**

C. Peri-operative management of bleeding **OR**
D. As a component of Immune tolerance induction (ITI)/Immune tolerance therapy (ITT) AND ONE of the following:
1. The patient has NOT had more than 33 months of ITT/ITI therapy **OR**
2. There is support for the continued use of ITT/ITI therapy (i.e., the patient has had a greater than or equal to 20% decrease in inhibitor level over the last 6 months and needs further treatment to eradicate inhibitors) (medical records required) **OR**

B. The patient has a diagnosis of hemophilia B AND BOTH of the following:
1. The patient has inhibitors to Factor IX **AND**
2. The requested agent is being used for ONE of the following:
A. On-demand use for bleeds AND ONE of the following:
1. The prescriber communicated with the patient (via any means) regarding the frequency and severity of the patient's bleeds and has verified that the patient does not have greater than 5 on-demand doses on hand **OR**
2. There is support for the patient having more than 5 on-demand doses on hand (supportive reasoning required) **OR**
B. Prophylaxis AND BOTH of the following:
1. ONE of the following:
A. The patient has tried and had an inadequate response to Immune Tolerance Induction (ITI) [Immune Tolerance Therapy (ITT)] **OR**
B. The patient has an inhibitor level greater than or equal to 200 BU (lab records required) **OR**
C. The patient is not a candidate for ITI **AND**
2. The patient will NOT be using the requested agent in combination with Feiba [activated prothrombin complex (aPCC)] used for prophylaxis (on-demand use of aPCC is acceptable) **OR**
C. Peri-operative management of bleeding **OR**
D. As a component of Immune tolerance induction (ITI)/Immune tolerance therapy (ITT) AND ONE of the following:
1. The patient has NOT had more than 33 months of ITT/ITI therapy **OR**
2. There is support for the continued use of ITT/ITI therapy (i.e., the patient has had a greater than or equal to 20% decrease in inhibitor level over the last 6 months and needs further treatment to eradicate inhibitors) (medical records required) **OR**

C. The patient has a diagnosis of congenital Factor VII deficiency AND the requested agent will be used for ONE of the following:
1. On-demand use for bleeds AND ONE of the following:
A. The prescriber communicated with the patient (via any means) regarding the frequency and severity of the patient's bleeds and has verified that the patient does not have greater than 5 on-demand doses on hand **OR**
B. There is support for the patient having more than 5 on-demand doses on hand (supportive reasoning required) **OR**
2. Prophylaxis **OR**
3. Perioperative use **OR**

	D. The patient has a diagnosis of Glanzmann's thrombasthenia AND BOTH of the following: 1. The patient is refractory to platelet transfusions **AND** 2. The requested agent will be used for ONE of the following: A. On-demand use for bleeds AND ONE of the following: 1. The prescriber communicated with the patient (via any means) regarding the frequency and severity of the patient's bleeds and has verified that the patient does not have greater than 5 on-demand doses on hand **OR** 2. There is support for the patient having more than 5 on-demand doses on hand (supportive reasoning required) **OR** B. Perioperative use **OR** E. The patient has a diagnosis of acquired hemophilia AND the requested agent will be used for ONE of the following: 1. On-demand use for bleeds AND ONE of the following: A. The prescriber communicated with the patient (via any means) regarding the frequency and severity of the patient's bleeds and has verified that the patient does not have greater than 5 on-demand doses on hand **OR** B. There is support for the patient having more than 5 on-demand doses on hand (supportive reasoning required) **OR** 2. Perioperative use **OR** F. The patient has another FDA labeled indication for the requested agent and route of administration **AND** 2. If the patient has an FDA labeled indication, ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. There is support for using the requested agent for the patient's age for the requested indication **OR** B. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND** 2. The prescriber is a specialist in the area of the patient's diagnosis (e.g., prescriber working in a hemophilia treatment center [HTC], hematologist with hemophilia experience) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 3. The patient will NOT be using the requested agent in combination with another Factor VIIa agent **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS, or DrugDex 1 or 2a level of evidence **Length of Approval:** Peri-operative dosing: 1 time per request; On-demand: up to 3 months; Prophylaxis: up to 12 months; ITT/ITI: up to 6 months, or up to a total of 33 months of ITT/ITI therapy, or requested duration - whichever is shortest;, all other indications: 3 months NOTE: If Quantity Limit applies please see Quantity Limit criteria
Sevenfact	**Sevenfact** will be approved when ALL of the following are met: 1. ONE of the following: A. The patient has a diagnosis of hemophilia A AND BOTH of the following: 1. The patient has inhibitors to Factor VIII **AND** 2. The requested agent is being used for on-demand use for bleeds **OR** B. The patient has a diagnosis of hemophilia B AND BOTH of the following: 1. The patient has inhibitors to Factor IX **AND** 2. The requested agent is being used for on-demand use for bleeds **OR**

	C. The patient has another FDA labeled indication for the requested agent and route of administration **AND** 2. If the patient has an FDA labeled indication, ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. There is support for using the requested agent for the patient's age for the requested indication **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis [e.g., prescriber working in a hemophilia treatment center (HTC), hematologist with hemophilia experience] or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient will NOT be using the requested agent in combination with another Factor VIIa agent **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 6. ONE of the following: A. The prescriber communicated with the patient (via any means) regarding the frequency and severity of the patient's bleeds and has verified that the patient does not have greater than 5 on-demand doses on hand **OR** B. There is support for the patient having more than 5 on-demand doses on hand (supportive reasoning required) **Length of Approval:** up to 3 months NOTE: If Quantity Limit applies, please see Quantity Limit Criteria

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
NovoSeven RT	**Quantity Limit for the requested agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit defined by BOTH of the following: A. The requested dose is within the FDA labeled dosing **AND** B. The requested quantity (number of doses) is appropriate based on intended use (e.g., on-demand, prophylaxis, perioperative) **OR** 2. There is support for exceeding the defined program quantity limit (dose and/or number of doses) (medical records required) **Length of Approval:** Peri-operative dosing: 1 time per request; On-demand: up to 3 months; Prophylaxis: up to 12 months; ITT/ITI: up to 6 months, or up to a total of 33 months of ITT/ITI therapy, or requested duration, whichever is shortest; up to 3 months for all other diagnoses
Sevenfact	**Quantity Limit for the Requested Agent(s)** will be approved when ONE of the following are met: 1. The requested quantity (dose) does NOT exceed the program quantity limit defined by BOTH of the following: A. The requested dose is within the FDA labeled dosing **AND** B. The requested quantity (number of doses) is appropriate based on intended use (e.g., on-demand) **OR** 2. There is support for exceeding the defined program quantity limit (dose and/or number of doses) (medical records required) **Length of Approval:** up to 3 months

• Program Summary: Dipeptidyl Peptidase-4 (DDP-4) Inhibitors and Combinations

Applies to:	☑ Commercial Formularies
Type:	☐ Prior Authorization ☑ Quantity Limit ☑ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
279925027003	Janumet	sitagliptin-metformin hcl tab	50-1000 MG ; 50-500 MG	60	Tablets	30	DAYS				
27992502707530	Janumet xr	Sitagliptin-Metformin HCl Tab ER 24HR 50-1000 MG	50-1000 MG	60	Tablets	30	DAYS				
27992502707520	Janumet xr	Sitagliptin-Metformin HCl Tab ER 24HR 50-500 MG	50-500 MG	30	Tablets	30	DAYS				
275500701003	Januvia	sitagliptin phosphate tab	100 MG ; 25 MG ; 50 MG	30	Tablets	30	DAYS				
279925024003	Jentadueto	linagliptin-metformin hcl tab	2.5-1000 MG ; 2.5-500 MG ; 2.5-850 MG	60	Tablets	30	DAYS				
27992502407520	Jentadueto xr	Linagliptin-Metformin HCl Tab ER 24HR 2.5-1000 MG	2.5-1000 MG	60	Tablets	30	DAYS				
27992502407530	Jentadueto xr	Linagliptin-Metformin HCl Tab ER 24HR 5-1000 MG	5-1000 MG	30	Tablets	30	DAYS				
279925021003	Kazano	alogliptin-metformin hcl tab	12.5-1000 MG ; 12.5-500 MG	30	Tablets	30	DAYS				
27992502607520	Kombiglyze xr	Saxagliptin-Metformin HCl Tab ER 24HR 2.5-1000 MG	2.5-1000 MG	60	Tablets	30	DAYS				
27992502607540	Kombiglyze xr	Saxagliptin-Metformin HCl Tab ER 24HR 5-1000 MG	5-1000 MG	30	Tablets	30	DAYS				
27992502607530	Kombiglyze xr	Saxagliptin-Metformin HCl Tab ER 24HR 5-500 MG	5-500 MG	30	Tablets	30	DAYS				
275500101003	Nesina	alogliptin benzoate tab	12.5 MG ; 25 MG ; 6.25 MG	30	Tablets	30	DAYS				
275500651003	Onglyza	saxagliptin hcl tab	2.5 MG ; 5 MG	30	Tablets	30	DAYS				
279940021003	Oseni	alogliptin-pioglitazone tab	12.5-15 MG ; 12.5-30 MG ; 12.5-45 MG ; 25-15 MG ; 25-30 MG ; 25-45 MG	30	Tablets	30	DAYS				
27550050000320	Tradjenta	Linagliptin Tab 5 MG	5 MG	30	Tablets	30	DAYS				
27550070000320	Zituvio	sitagliptin tab	25 MG	30	Tablets	30	DAYS				
27550070000330	Zituvio	sitagliptin tab	50 MG	30	Tablets	30	DAYS				
27550070000340	Zituvio	sitagliptin tab	100 MG	30	Tablets	30	DAYS				

STEP THERAPY CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
1-Step Through Preferred	

Preferred Agents	Non-preferred Agents
Januvia (sitagliptin) **Janumet** (sitagliptin/metformin) **Janumet XR** (sitagliptin/metformin ER)	**Alogliptin** **Alogliptin/metformin** **Alogliptin/pioglitazone** **Jentadueto** (linagliptin/metformin) **Jentadueto XR** (linagliptin/metformin ER) **Kazano** (alogliptin/metformin) **Kombiglyze XR** (saxagliptin/metformin ER)* **Nesina** (alogliptin) **Onglyza** (saxagliptin)* **Oseni** (alogliptin/pioglitazone) **Tradjenta** (linagliptin) **Zituvio** (sitagliptin)

* available as generic; not a prerequisite or target in the step therapy program

Target Agent(s) will be approved when ALL of the following are met:

1. ONE of the following:
   - A. The patient is currently being treated with the requested agent as indicated by ALL of the following:
     1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
     2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
     3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
   - B. The patient's medication history includes use of a preferred DPP-4 inhibitor agent **OR**
   - C. BOTH of the following:
     1. The prescriber has stated that the patient has tried a preferred DPP-4 inhibitor agent **AND**
     2. The preferred DPP-4 inhibitor agent was discontinued due to lack of effectiveness or an adverse event **OR**
   - D. The patient has an intolerance or hypersensitivity to sitagliptin that is not expected to occur with the requested agent **OR**
   - E. The patient has an FDA labeled contraindication to sitagliptin that is not expected to occur with the requested agent **OR**
   - F. The prescriber has provided documentation that the preferred DPP-4 inhibitors cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**
2. The patient will NOT be using the requested agent in combination with another DPP-4 inhibitor/combination agent for the requested indication **AND**
3. The patient will NOT be using the requested agent in combination with a GLP-1 agent

Length of Approval: 12 months

NOTE: If Quantity Limit program also applies, please refer to Quantity Limit criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval

Universal QL	**Quantity limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: A. BOTH of the following: 1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **OR** B. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 2. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** C. BOTH of the following: 1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **Length of Approval**: up to 12 months

• Program Summary: Egrifta (tesamorelin)

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
30150085102130	Egrifta sv	Tesamorelin Acetate For Inj 2 MG (Base Equiv)	2 MG	30	Vials	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has a diagnosis of human immunodeficiency virus (HIV) infection **AND** 2. The requested agent is being prescribed to reduce excess abdominal fat in HIV-associated lipodystrophy **AND** 3. If the patient has an FDA labeled indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. There is support for using the requested agent for the patient's age for the requested indication **AND** 4. The prescriber has measured and recorded baseline (prior to therapy with the requested agent) visceral adipose tissue (VAT) and waist circumference **AND** 5. The patient is currently being treated with antiretroviral therapy (ART) **AND** 6. The prescriber is a specialist in the area of the patient's diagnosis (e.g., infectious disease, HIV specialist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 7. The patient does NOT have any FDA labeled contraindications to the requested agent

	Length of Approval: 6 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND** 2. The patient is currently being treated with antiretroviral therapy (ART) **AND** 3. The patient has had improvements or stabilization with the requested agent as indicated by ONE of the following: A. The patient has achieved or maintained an 8% decrease in visceral adipose tissue (VAT) from baseline (prior to therapy with the requested agent) **OR** B. The patient has maintained or had a decrease in their waist circumference from baseline (prior to therapy with the requested agent) **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., infectious disease, HIV specialist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity limit for the Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: A. BOTH of the following: 1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **OR** B. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 2. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **Length of Approval:** up to 12 months

• Program Summary: Elmiron

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☐ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Final Module	Target Agent GPI	Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Targeted NDCs When Exclusions Exist	Final Age Limit	Preferred Status	Effective Date
	565000601001	Elmiron	pentosan polysulfate sodium caps	100 MG	M ; N ; O ; Y				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. The requested agent will be used for the relief of bladder pain or discomfort associated with interstitial cystitis **AND** 2. The patient has tried and had an inadequate response to behavioral modification or self-care practices **AND** 3. ONE of the following: A. The patient has tried and had an inadequate response to amitriptyline, cimetidine, or hydroxyzine **OR** B. The patient has an intolerance or hypersensitivity to amitriptyline, cimetidine, or hydroxyzine **OR** C. The patient has an FDA labeled contraindication to amitriptyline, cimetidine, and hydroxyzine **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on the requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that amitriptyline, cimetidine, and hydroxyzine cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 4. The patient has had an eye exam with an eye specialist (e.g., optometrist, ophthalmologist) prior to starting the requested agent **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 6. The requested quantity (dose) does not exceed the FDA labeled dose for the requested indication **Length of Approval:** 6 months **Renewal Evaluation** **Target Agent(s)** will be approved for renewal when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND** 2. The patient has had clinical benefit with the requested agent (e.g., decreased bladder pain, decreased frequency or urgency of urination) **AND** 3. The patient has had an eye exam with an eye specialist (e.g., optometrist, ophthalmologist) within the last 12 months **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**

	5. The requested quantity (dose) does not exceed the FDA labeled dose for the requested indication **Length of Approval:** 12 months

● Program Summary: Endari (L-glutamine)

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☐ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Final Module	Target Agent GPI	Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Targeted NDCs When Exclusions Exist	Final Age Limit	Preferred Status	Effective Date
	828010200030	Endari	glutamine (sickle cell) powd pack	5 GM	M ; N ; O ; Y				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has a diagnosis of sickle cell disease **AND** 2. The patient is using the requested agent to reduce the acute complications of sickle cell disease **AND** 3. If the patient has an FDA labeled indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. There is support for using the requested agent for the patient's age **AND** 4. ONE of the following: A. The patient has tried and had an inadequate response to hydroxyurea **OR** B. The patient has an intolerance or hypersensitivity to hydroxyurea **OR** C. The patient has an FDA labeled contraindication to hydroxyurea **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that hydroxyurea cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 5. ONE of the following: A. The patient will NOT be using the requested agent in combination with Adakevo (crizanlizumab-tmca) OR Oxbryta (voxelotor) **OR** B. There is support for use of the requested agent in combination with Adakveo (crizanlizumab-tmca) or Oxbryta (voxelotor) **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 7. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **Length of Approval:** 12 months

	Renewal Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved through the plan's Prior Authorization process (Note: patients not previously approved for the requested agent will require initial evaluation review) **AND** 2. The patient has had clinical benefit with the requested agent (i.e., reduction in acute complications of sickle cell disease since initiating therapy with the requested agent) **AND** 3. ONE of the following: A. The patient will NOT be using the requested agent in combination with Adakevo (crizanlizumab-tmca) OR Oxbryta (voxelotor) **OR** B. There is support for use of the requested agent in combination with Adakevo (crizanlizumab-tmca) or Oxbryta (voxelotor) **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 5. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **Length of Approval:** 12 months

• Program Summary: Erythropoietins

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☐ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Final Module	Target Agent GPI	Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Targeted NDCs When Exclusions Exist	Final Age Limit	Preferred Status	Effective Date
	824010151020	Aranesp albumin free	darbepoetin alfa soln inj	100 MCG/ML ; 200 MCG/ML ; 25 MCG/ML ; 40 MCG/ML ; 60 MCG/ML	M ; N ; O ; Y				
	8240101510E5	Aranesp albumin free	darbepoetin alfa soln prefilled syringe	10 MCG/0.4ML ; 100 MCG/0.5ML ; 150 MCG/0.3ML ; 200 MCG/0.4ML ; 25 MCG/0.42ML ; 300 MCG/0.6ML ; 40 MCG/0.4ML ; 500 MCG/ML ; 60 MCG/0.3ML	M ; N ; O ; Y				
	824010200020	Epogen ; Procrit	epoetin alfa inj	10000 UNIT/ML ; 2000 UNIT/ML ; 20000 UNIT/ML ; 3000 UNIT/ML ; 4000 UNIT/ML ; 40000 UNIT/ML	M ; N ; O ; Y				
	8240104010E5	Mircera	methoxy peg-epoetin beta soln prefilled syr	100 MCG/0.3ML ; 120 MCG/0.3ML ; 150 MCG/0.3ML ; 200 MCG/0.3ML ; 30 MCG/0.3ML ; 50 MCG/0.3ML ; 75 MCG/0.3ML	M ; N ; O ; Y				
	824010200420	Retacrit	epoetin alfa-epbx inj	10000 UNIT/ML ; 2000 UNIT/ML ; 20000 UNIT/2ML ; 20000 UNIT/ML ; 3000 UNIT/ML ; 4000 UNIT/ML ; 40000 UNIT/ML	M ; N ; O ; Y				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval

Target Agent(s) will be approved when BOTH of the following are met:

1. The patient's hemoglobin was measured within the previous 4 weeks **AND**
2. ONE of the following:
    A. The patient will use the requested agent as part of dialysis AND ONE of the following:
        1. The patient is initiating an erythropoietin stimulating agent (ESA) AND the patient's hemoglobin level is less than 10 g/dL **OR**
        2. The patient is stabilized on an ESA AND the patient's hemoglobin is less than or equal to 11 g/dL **OR**
    B. ALL of the following:
        1. ONE of the following:
            A. The requested agent is being prescribed to reduce the possibility of allogeneic blood transfusion in a surgery patient AND the patient's hemoglobin level is greater than 10 g/dL but less than or equal to 13 g/dL **OR**
            B. The requested agent is being prescribed for anemia due to myelosuppressive chemotherapy for a non-myeloid malignancy AND ALL of the following:
                1. The requested agent is NOT Mircera **AND**
                2. ONE of the following:
                    A. The patient is initiating an erythropoietin stimulating agent (ESA) AND the patient's hemoglobin level is less than 10 g/dL **OR**
                    B. The patient is stabilized on an ESA AND the patient's hemoglobin is less than or equal to 12 g/dL **AND**
                3. The patient is concurrently treated with chemotherapy (with or without radiation) **AND**
                4. Chemotherapy is being used for palliative intent **AND**
                5. The patient's serum ferritin and transferrin saturation have been evaluated within the previous 4 weeks AND BOTH of the following:
                    A. The patient's serum ferritin is NOT greater than 800 ng/mL **AND**
                    B. The patient's transferrin saturation is NOT greater than 50% **OR**
            C. The requested agent is being prescribed for anemia associated with chronic kidney disease in a patient NOT on dialysis AND ALL of the following:
                1. ONE of the following:
                    A. The patient is initiating an erythropoietin stimulating agent (ESA) AND the patient's hemoglobin level is less than 10 g/dL **OR**
                    B. The patient is stabilized on an ESA AND the patient's hemoglobin is less than or equal to 11 g/dL **AND**
                2. The rate of hemoglobin decline is likely to result in a red blood cell (RBC) transfusion **AND**
                3. The intent of therapy is to reduce the risk of alloimmunization and/or other RBC transfusion related risks **OR**
            D. The requested agent is being prescribed for anemia due to myelodysplastic syndrome, or for anemia resulting from zidovudine treatment of HIV infection AND ONE of the following:
                1. The patient is initiating an erythropoietin stimulating agent (ESA) AND the patient's hemoglobin level is less than 12 g/dL **OR**
                2. The patient is stabilized on an ESA AND the patient's hemoglobin is less than or equal to 12 g/dL **OR**
            E. The requested agent is being prescribed for another FDA labeled indication or another indication that is supported in compendia AND the patient's hemoglobin level is within the FDA labeling or compendia recommended range for the requested indication for patients initiating ESA therapy OR for patients stabilized on therapy for the requested indication **AND**

	2. The patient's serum ferritin and transferrin saturation have been evaluated within the previous 4 weeks **AND** 3. ONE of the following: A. The patient's serum ferritin is greater than or equal to 100 ng/mL AND the patient's transferrin saturation is greater than or equal to 20% **OR** B. The patient has started supplemental iron therapy **AND** 4. If the patient has an FDA labeled indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. There is support for using the requested agent for the patient's age for the requested indication **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS, or DrugDex 1 or 2a level of evidence, NCCN 1 or 2a recommended use **Length of Approval**: 1 month for allogenic blood transfusion in a surgery patient; 6 months for anemia due to myelosuppressive chemotherapy for a non-myeloid malignancy 12 months for anemia associated with chronic kidney disease in patients on/not on dialysis, anemia due to myelodysplastic syndrome, anemia resulting from zidovudine treatment of HIV infection 6 months for all other diagnoses

• Program Summary: Factor VIII and von Willebrand Factor

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

QUANTITY LIMIT INFORMATION

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Additional QL Information	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
851000102521	Advate ; Kovaltry	antihemophilic factor recomb (rahf-pfm) for inj	1000 UNIT ; 1500 UNIT ; 2000 UNIT ; 250 UNIT ; 3000 UNIT ; 4000 UNIT ; 500 UNIT	Dependent on patient weight and number of doses			
851000104021	Adynovate	antihemophilic factor recomb pegylated for inj	1000 UNIT ; 1500 UNIT ; 2000 UNIT ; 250 UNIT ; 3000 UNIT ; 500 UNIT ; 750 UNIT	Dependent on patient weight and number of doses			
851000105564	Afstyla	antihemophilic fact rcmb single chain for inj kit	1000 UNIT ; 1500 UNIT ; 2000 UNIT ; 250 UNIT ; 2500 UNIT ; 3000 UNIT ; 500 UNIT	Dependent on patient weight and number of doses			
851000151021	Alphanate ; Humate-p	antihemophilic factor/vwf (human) for inj	1000 UNIT ; 1000-2400 UNIT ; 1500 UNIT ; 2000 UNIT ; 250 UNIT ; 250-600 UNIT ; 500 UNIT ; 500-1200 UNIT	Dependent on patient weight and number of doses			
851000103121	Altuviiio	antihemophilic fact rcmb fc-vwf-xten-ehtl for inj	1000 UNIT ; 2000 UNIT ; 250 UNIT ; 3000 UNIT ; 4000 UNIT ; 500 UNIT ; 750 UNIT	Dependent on patient weight and number of doses			
851000103021	Eloctate	antihemophilic factor rcmb (bdd-rfviiifc) for inj	1000 UNIT ; 1500 UNIT ; 2000 UNIT ; 250 UNIT ; 3000 UNIT ; 4000 UNIT ; 500 UNIT ; 5000 UNIT ; 6000 UNIT ; 750 UNIT	Dependent on patient weight and number of doses			

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Additional QL Information	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
851000103521	Esperoct	antihemophilic factor recomb glycopeg-exei for inj	1000 UNIT ; 1500 UNIT ; 2000 UNIT ; 3000 UNIT ; 500 UNIT	Dependent on patient weight and number of doses			
851000100021	Hemofil m ; Koate ; Koate-dvi	antihemophilic factor (human) for inj	1000 UNIT ; 1700 UNIT ; 250 UNIT ; 500 UNIT	Dependent on patient weight and number of doses			
851000104121	Jivi	antihemophil fact rcmb(bdd-rfviii peg-aucl) for inj ; antihemophil fact rcmb(bdd-rfviii peg-aucl)for inj	1000 UNIT ; 2000 UNIT ; 3000 UNIT ; 500 UNIT	Dependent on patient weight and number of doses			
851000102064	Kogenate fs	antihemophilic factor recomb (rfviii) for inj kit	1000 UNIT ; 2000 UNIT ; 250 UNIT ; 3000 UNIT ; 500 UNIT	Dependent on patient weight and number of doses			
851000103321	Novoeight	antihemophilic fact rcmb (bd trunc-rfviii) for inj	1000 UNIT ; 1500 UNIT ; 2000 UNIT ; 250 UNIT ; 3000 UNIT ; 500 UNIT	Dependent on patient weight and number of doses			
851000102264	Nuwiq	antihemophil fact rcmb (bdd-rfviii,sim) for inj kit ; antihemophil fact rcmb(bdd-rfviii,sim) for inj kit	1000 UNIT ; 1500 UNIT ; 2000 UNIT ; 250 UNIT ; 2500 UNIT ; 3000 UNIT ; 4000 UNIT ; 500 UNIT	Dependent on patient weight and number of doses			
851000102221	Nuwiq	antihemophilic fact rcmb (bdd-rfviii,sim) for inj ; antihemophilic factor rcmb (bdd-rfviii,sim) for inj	1000 UNIT ; 1500 UNIT ; 2000 UNIT ; 250 UNIT ; 2500 UNIT ; 3000 UNIT ; 4000 UNIT ; 500 UNIT	Dependent on patient weight and number of doses			
851000102021	Recombinate	antihemophilic factor recomb (rfviii) for inj	1241 -1800 UNIT ; 1801 -2400 UNIT ; 220 -400 UNIT ; 401 -800 UNIT ; 801 -1240 UNIT	Dependent on patient weight and number of doses			
851000702021	Vonvendi	von willebrand factor (recombinant) for inj	1300 UNIT ; 650 UNIT	Dependent on patient weight and number of doses			
851000151064	Wilate	antihemophilic factor/vwf (human) for inj	1000-1000 UNIT ; 500-500 UNIT	Dependent on patient weight and number of doses			
851000102664	Xyntha ; Xyntha solofuse	antihemophil fact rcmb (bdd-rfviii,mor) for inj kit ; antihemophil fact rcmb(bdd-rfviii,mor) for inj kit	1000 UNIT ; 2000 UNIT ; 250 UNIT ; 3000 UNIT ; 500 UNIT	Dependent on patient weight and number of doses			

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Effective until 10/31/24 for:** **Those with an original PA date prior to 11/1/23 seeking reauthorization AND that have not started a new plan year**

Preferred and Non-Preferred Agents to be determined by client

Preferred Agents for Hemophilia A	Non-Preferred Agents for Hemophilia A
Advate Adynovate Afstyla Eloctate Esperoct Jivi Kogenate FS Kovaltry NovoEight Nuwiq Recombinate Vonvendi Wilate Xyntha/Xyntha solofuse Alphanate Altuviiio Hemofil-M Humate-P Koāte	None

Preferred Agents for von Willebrand disease	Non-Preferred Agents for von Willebrand disease
Vonvendi Wilate Alphanate Humate-P	None

Target Agent(s) will be approved when ALL of the following are met:

1. ONE of the following:
    A. The requested agent is eligible for continuation of therapy AND ONE of the following:

Agents Eligible for Continuation of Therapy
All target agents are eligible for continuation of therapy

        1. Information has been provided that indicates the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR**
        2. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR**

    B. The patient has a diagnosis of hemophilia A (also known as Factor VIII deficiency or classic hemophilia) AND ONE of the following:
        1. The patient is currently experiencing a bleed AND BOTH of the following:
            A. The patient is out of medication **AND**
            B. The patient needs to receive a ONE TIME emergency supply of medication **OR**
        2. BOTH of the following:
            A. The requested agent is being used for ONE of the following:
                1. Prophylaxis AND the patient will NOT be using the requested agent in combination with Hemlibra (emicizumab-kxwh) **OR**
                2. As a component of Immune Tolerance Therapy (ITT)/Immune Tolerance Induction (ITI) AND BOTH of the following:

A. The patient will NOT be using the requested agent in combination with Hemlibra (emicizumab-kxwh) **AND**
B. ONE of the following: (medical records required)
1. The patient has NOT had more than 33 months of ITT/ITI therapy **OR**
2. Information has been provided supporting the continued use of ITT/ITI therapy (i.e., the patient has had a greater than or equal to 20% decrease in inhibitor level over the last 6 months and needs further treatment to eradicate inhibitors) **OR**

3. On-demand use for bleeds **OR**
4. Peri-operative management of bleeding **AND**

B. If the client has a preferred agent(s), then ONE of the following:
1. The requested agent is a preferred agent **OR**
2. The patient has tried and had an inadequate response to ALL of the preferred agent(s) for the requested indication **OR**
3. The patient has an intolerance or hypersensitivity to ALL of the preferred agent(s) for the requested indication **OR**
4. The patient has an FDA labeled contraindication to ALL preferred agents for the requested indication **OR**
5. The patient is currently being treated with the requested agent as indicated by ALL of the following:
A. A statement by the prescriber that the patient is currently taking the requested agent **AND**
B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**

6. The prescriber has provided documentation the preferred agent(s) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR**

C. The patient has a diagnosis of von Willebrand disease (VWD) AND ALL of the following:
1. ONE of the following:
A. The patient is currently experiencing a bleed AND BOTH of the following:
1. The patient is out of medication **AND**
2. The patient needs to receive a ONE TIME emergency supply of medication **OR**

B. The patient has type 1, 2A, 2M or 2N VWD AND ONE of the following:
1. The patient has tried and had an inadequate response to desmopressin (e.g., DDAVP injection, Stimate nasal spray) **OR**
2. The patient did not respond to a DDAVP trial with 1 and 4 hour post infusion bloodwork **OR**
3. The patient has an intolerance or hypersensitivity to desmopressin **OR**
4. The patient has an FDA labeled contraindication to desmopressin **OR**
5. The prescriber has provided information supporting why the patient cannot use desmopressin (e.g., shortage in marketplace) **OR**
6. The patient is currently being treated with the requested agent as indicated by ALL of the following:
A. A statement by the prescriber that the patient is currently taking the requested agent **AND**
B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**

C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**

7. The prescriber has provided documentation desmopressin (e.g., DDAVP injection, Stimate nasal spray) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR**

C. The patient has type 2B or 3 VWD **AND**

2. The requested agent will be used for ONE of the following:
   A. Prophylaxis AND ONE of the following:
      1. The requested agent is Vonvendi AND ONE of the following:
         A. The patient has severe Type 3 VWD **OR**
         B. The patient has another subtype of VWD AND the subtype is FDA approved for prophylaxis use **OR**
      2. The requested agent is NOT Vonvendi **OR**
   B. On-demand use for bleeds **OR**
   C. Peri-operative management of bleeding **AND**
3. If the client has a preferred agent(s), then ONE of the following:
   A. The requested agent is a preferred agent **OR**
   B. The patient has tried and had an inadequate response to ALL of the preferred agent(s) for the requested indication **OR**
   C. The patient has an intolerance or hypersensitivity to ALL of the preferred agent(s) for the requested indication **OR**
   D. The patient has an FDA labeled contraindication to ALL preferred agents for the requested indication **OR**
   E. The patient is currently being treated with the requested agent as indicated by ALL of the following:
      1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
      2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
      3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
   F. The prescriber has provided documentation the preferred agent(s) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**

2. If the patient has an FDA approved indication, ONE of the following:
   A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**
   B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND**
3. The prescriber is a specialist in the area of the patient's diagnosis [e.g., prescriber working in a hemophilia treatment center (HTC), hematologist with hemophilia experience] or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**
4. ONE of the following:
   A. The patient will NOT be using the requested agent in combination with a nonsteroidal anti-inflammatory agent (NSAID) (e.g., aspirin, ibuprofen) other than cyclooxygenase-2 (COX-2) inhibitors (e.g., celecoxib) NOTE: for the purposes of this criteria COX-2 inhibitors will be accepted for concomitant use **OR**
   B. The prescriber has provided information in support of using an NSAID for this patient **AND**
5. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**
6. The prescriber must provide the actual prescribed dose with ALL of the following:
   A. Patient's weight **AND**
   B. Intended use/regimen: (e.g., prophylaxis, ITT/ITI, on-demand, peri-operative) **AND**
   C. If the patient has a diagnosis of hemophilia A BOTH of the following:

1. Severity of the factor deficiency (i.e., severe is less than 1% factor activity, moderate is greater than or equal to 1 to less than or equal to 5% factor activity, mild is greater than 5 to 40% factor activity) **AND**
2. Inhibitor status **AND**

7. ONE of the following:
   A. The patient will NOT be using the requested agent in combination with another agent in the same category (e.g., Factor VIII agents, Factor VIII and von Willebrand Factor combination agents) included in this program **OR**
   B. Information has been provided supporting the use of more than one unique agent in the same category (medical records required)

Compendia Allowed: AHFS, or DrugDex 1 or 2a level of evidence

Length of Approval: One time emergency use: up to 2 weeks Peri-operative dosing: 1 time per request On-demand: up to 3 months Prophylaxis: up to 6 months ITT/ITI: up to 6 months

NOTE: If Quantity Limit applies, please see Quantity Limit criteria

Renewal Evaluation

Target Agent(s) will be approved when ALL of the following are met:

1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process (if current request is for ONE TIME emergency use or if patient ONLY has previous approval(s) for emergency use, must use Initial Evaluation) **AND**
2. If the patient is using the requested agent for prophylaxis, then ONE of the following:
   A. The patient has a diagnosis of hemophilia A AND the patient will NOT be using the requested agent in combination with Hemlibra (emicizumab-kxwh) **OR**
   B. The patient has another diagnosis **AND**
3. The prescriber is a specialist in the area of the patient's diagnosis [e.g., prescriber working in a hemophilia treatment center (HTC), hematologist with hemophilia experience] or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**
4. ONE of the following:
   A. The patient will NOT be using the requested agent in combination with a nonsteroidal anti-inflammatory agent (NSAID) (e.g., aspirin, ibuprofen) other than cyclooxygenase-2 (COX-2) inhibitors (e.g., celecoxib) NOTE: for the purposes of this criteria COX-2 inhibitors will be accepted for concomitant use **OR**
   B. The prescriber has provided information in support of using an NSAID for this patient **AND**
5. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**
6. The prescriber must provide the actual prescribed dose with ALL of the following:
   A. Patient's weight **AND**
   B. Intended use/regimen: (e.g., prophylaxis, ITT/ITI, on-demand, peri-operative) **AND**
   C. If the patient has a diagnosis of hemophilia A BOTH of the following:
      1. Severity of the factor deficiency (i.e., severe is less than 1% factor activity, moderate is greater than or equal to 1 to less than or equal to 5% factor activity, mild is greater than 5 to 40% factor activity) **AND**
      2. Inhibitor status **AND**
7. ONE of the following:
   A. The prescriber communicated with the patient (via any means) regarding the frequency and severity of the patient's bleeds and has verified that the patient does not have greater than 5 on-demand doses on hand **OR**
   B. The prescriber has provided information in support of the patient having more than 5 on-demand doses on hand **AND**

8. ONE of the following:
    A. The patient will NOT be using the requested agent in combination with another agent in the same category (e.g., Factor VIII agents, Factor VIII and von Willebrand Factor combination agents) included in this program **OR**
    B. Information has been provided supporting the use of more than one unique agent in the same category (medical records required) **AND**
9. If the patient is using Immune Tolerance Therapy (ITT)/Immune Tolerance Induction (ITI), then ONE of the following:
    A. The patient has NOT had more than 33 months of ITT/ITI therapy **OR**
    B. Information has been provided supporting the continued use of ITT/ITI therapy (i.e., the patient has had a greater than or equal to 20% decrease in inhibitor level over the last 6 months and needs further treatment to eradicate inhibitors) (medical records required)

Length of Approval: Peri-operative: 1 time per request On-demand: up to 3 months Prophylaxis: up to 12 months ITT/ITI: up to 6 months, or up to a total of 33 months of ITT/ITI therapy, or requested duration, whichever is shortest

NOTE: If Quantity Limit applies, please see Quantity Limit criteria

Initial Evaluation

Effective 11/1/23 for:
Those who were approved through criteria after 11/1/23
Those who have started a new plan year since last authorization

Preferred and Non-Preferred Agents to be determined by client

Preferred Agents for Hemophilia A	Non-Preferred Agents for Hemophilia A
Advate Adynovate Afstyla Eloctate Esperoct Jivi Kogenate FS Kovaltry NovoEight Nuwiq Recombinate Wilate Xyntha/Xyntha solofuse Alphanate Altuviiio Hemofil-M Humate-P Koāte	None

Preferred Agents for von Willebrand disease	Non-Preferred Agents for von Willebrand disease
Vonvendi Wilate Alphanate Humate-P	None

Target Agent(s) will be approved when ALL of the following are met:

1. ONE of the following:
   A. The requested agent is eligible for continuation of therapy AND ONE of the following:

Agents Eligible for Continuation of Therapy
All target agents are eligible for continuation of therapy

      1. The patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR**
      2. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR**

   B. BOTH of the following:
      1. ONE of the following:
         A. The patient has a diagnosis of hemophilia A (also known as Factor VIII deficiency or classic hemophilia) AND ONE of the following:
            1. The patient is currently experiencing a bleed AND BOTH of the following:
               A. The patient is out of medication **AND**
               B. The patient needs to receive a ONE TIME emergency supply of medication **OR**
            2. ALL of the following:
               A. The requested agent is FDA labeled or compendia supported for a diagnosis of hemophilia A **AND**
               B. The requested agent is being used for ONE of the following:
                  1. Prophylaxis AND the patient will NOT be using the requested agent in combination with Hemlibra (emicizumab-kxwh) **OR**
                  2. As a component of Immune Tolerance Therapy (ITT)/Immune Tolerance Induction (ITI) AND BOTH of the following:
                     A. The patient will NOT be using the requested agent in combination with Hemlibra (emicizumab-kxwh) **AND**
                     B. ONE of the following: (medical records required)
                        1. The patient has NOT had more than 33 months of ITT/ITI therapy **OR**
                        2. There is support for the continued use of ITT/ITI therapy (i.e., the patient has had a greater than or equal to 20% decrease in inhibitor level over the last 6 months and needs further treatment to eradicate inhibitors) **OR**
                  3. On-demand use for bleeds **OR**
                  4. Peri-operative management of bleeding **AND**
               C. If the client has a preferred agent(s), then ONE of the following:
                  1. The requested agent is a preferred agent **OR**
                  2. The patient has tried and had an inadequate response to ALL of the preferred agent(s) for the requested indication **OR**
                  3. The patient has an intolerance or hypersensitivity to ALL of the preferred agent(s) for the requested indication **OR**

4. The patient has an FDA labeled contraindication to ALL of the preferred agents for the requested indication **OR**
5. The patient is currently being treated with the requested agent as indicated by ALL of the following:
    A. A statement by the prescriber that the patient is currently taking the requested agent **AND**
    B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
    C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
6. The prescriber has provided documentation the preferred agent(s) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR**

B. The patient has a diagnosis of von Willebrand disease (VWD) AND ALL of the following:
    1. The requested agent is FDA labeled or compendia supported for a diagnosis of von Willebrand disease **AND**
    2. ONE of the following:
        A. The patient is currently experiencing a bleed AND BOTH of the following:
            1. The patient is out of medication **AND**
            2. The patient needs to receive a ONE TIME emergency supply of medication **OR**
        B. The patient has type 1, 2A, 2M or 2N VWD AND ONE of the following:
            1. The patient has tried and had an inadequate response to desmopressin (e.g., DDAVP injection, Stimate nasal spray) **OR**
            2. The patient did not respond to a DDAVP trial with 1 and 4 hour post infusion bloodwork **OR**
            3. The patient has an intolerance or hypersensitivity to desmopressin **OR**
            4. The patient has an FDA labeled contraindication to desmopressin **OR**
            5. The patient cannot use desmopressin (e.g., shortage in marketplace) **OR**
            6. The patient is currently being treated with the requested agent as indicated by ALL of the following:
                A. A statement by the prescriber that the patient is currently taking the requested agent **AND**
                B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
                C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
            7. The prescriber has provided documentation desmopressin (e.g., DDAVP injection, Stimate nasal spray) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an

adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR**

C. The patient has type 2B or 3 VWD **AND**

3. The requested agent will be used for ONE of the following:
   A. Prophylaxis AND ONE of the following:
      1. The requested agent is Vonvendi AND ONE of the following:
         A. The patient has severe Type 3 VWD **OR**
         B. The patient has another subtype of VWD AND the subtype is FDA approved for prophylaxis use **OR**
      2. The requested agent is NOT Vonvendi **OR**
   B. On-demand use for bleeds **OR**
   C. Peri-operative management of bleeding **AND**
4. If the client has a preferred agent(s), then ONE of the following:
   A. The requested agent is a preferred agent **OR**
   B. The patient has tried and had an inadequate response to ALL of the preferred agent(s) for the requested indication **OR**
   C. The patient has an intolerance or hypersensitivity to ALL of the preferred agent(s) for the requested indication **OR**
   D. The patient has an FDA labeled contraindication to ALL of the preferred agents for the requested indication **OR**
   E. The patient is currently being treated with the requested agent as indicated by ALL of the following:
      1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
      2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
      3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
   F. The prescriber has provided documentation the preferred agent(s) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**

2. If the patient has an FDA labeled indication, ONE of the following:
   A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**
   B. There is support for using the requested agent for the patient's age for the requested indication **AND**

2. The prescriber is a specialist in the area of the patient's diagnosis [e.g., prescriber working in a hemophilia treatment center (HTC), hematologist with hemophilia experience] or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**
3. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**
4. The prescriber must provide the actual prescribed dose with ALL of the following:
   A. Patient's weight **AND**
   B. Intended use/regimen: (e.g., prophylaxis, ITT/ITI, on-demand, peri-operative) **AND**
   C. If the patient has a diagnosis of hemophilia A BOTH of the following:

1. Severity of the factor deficiency (i.e., severe is less than 1% factor activity, moderate is greater than or equal to 1 to less than or equal to 5% factor activity, mild is greater than 5 to 40% factor activity) **AND**
2. Inhibitor status **AND**

5. ONE of the following:
   A. The patient will NOT be using the requested agent in combination with another agent in the same category (e.g., Factor VIII agents, Factor VIII and von Willebrand Factor combination agents) included in this program **OR**
   B. There is support for the use of more than one unique agent in the same category (medical records required)

Compendia Allowed: AHFS, or DrugDex 1 or 2a level of evidence

Length of Approval: One time emergency use: up to 2 weeks, Peri-operative dosing: 1 time per request, On-demand: up to 3 months, Prophylaxis: up to 12 months, ITT/ITI: up to 6 months - or up to a total of 33 months ITT/ITI therapy, or requested duration, whichever is shortest

NOTE: If Quantity Limit applies, please see Quantity Limit criteria

Renewal Evaluation

Target Agent(s) will be approved when ALL of the following are met:

1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process (if current request is for ONE TIME emergency use or if patient ONLY has previous approval(s) for emergency use, must use Initial Evaluation) **AND**
2. If the patient is using the requested agent for prophylaxis, then ONE of the following:
   A. The patient has a diagnosis of hemophilia A AND the patient will NOT be using the requested agent in combination with Hemlibra (emicizumab-kxwh) **OR**
   B. The patient has another diagnosis **AND**
3. The prescriber is a specialist in the area of the patient's diagnosis [e.g., prescriber working in a hemophilia treatment center (HTC), hematologist with hemophilia experience] or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**
4. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**
5. The prescriber must provide the actual prescribed dose with ALL of the following:
   A. Patient's weight **AND**
   B. Intended use/regimen: (e.g., prophylaxis, ITT/ITI, on-demand, peri-operative) **AND**
   C. If the patient has a diagnosis of hemophilia A BOTH of the following:
      1. Severity of the factor deficiency (i.e., severe is less than 1% factor activity, moderate is greater than or equal to 1 to less than or equal to 5% factor activity, mild is greater than 5 to 40% factor activity) **AND**
      2. Inhibitor status **AND**
6. ONE of the following:
   A. The prescriber communicated with the patient (via any means) regarding the frequency and severity of the patient's bleeds and has verified that the patient does not have greater than 5 on-demand doses on hand **OR**
   B. There is support for the patient having more than 5 on-demand doses on hand **AND**
7. ONE of the following:
   A. The patient will NOT be using the requested agent in combination with another agent in the same category (e.g., Factor VIII agents, Factor VIII and von Willebrand Factor combination agents) included in this program **OR**
   B. There is support for the use of more than one unique agent in the same category (medical records required) **AND**

	8. If the patient is using Immune Tolerance Therapy (ITT)/Immune Tolerance Induction (ITI), then BOTH of the following: A. The patient will NOT be using the requested agent in combination with Hemlibra (emicizumab-kxwh) **AND** B. ONE of the following (medical records required): 1. The patient has NOT had more than 33 months of ITT/ITI therapy **OR** 2. There is support for the continued use of ITT/ITI therapy (i.e., the patient has had a greater than or equal to 20% decrease in inhibitor level over the last 6 months and needs further treatment to eradicate inhibitors) **Length of Approval:** Peri-operative dosing: 1 time per request, On-demand: up to 3 months, Prophylaxis: up to 12 months, ITT/ITI: up to 6 months, or up to a total of 33 months of ITT/ITI therapy, or requested duration, whichever is shortest NOTE: If Quantity Limit applies, please see Quantity Limit criteria

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity Limit for the requested agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit defined by BOTH of the following: A. The requested dose is within the FDA labeled dosing **AND** B. The requested quantity (number of doses) is appropriate based on intended use (e.g., prophylaxis, ITT/ITI, on-demand, peri-operative) **OR** 2. There is support for exceeding the defined program quantity limit (dose and/or number of doses) (medical records required) **Length of Approval:** For initial one-time emergency use: up to 2 weeks Prophylaxis: up to 12 months Both initial and renewal peri-operative dosing: 1 time per request Both initial and renewal on-demand: up to 3 months Both initial and renewal: ITT/ITI: up to 6 months, or up to a total of 33 months of ITT/ITI therapy, or requested duration, whichever is shortest

• Program Summary: Filspari (sparsentan)

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
56483065000320	Filspari	sparsentan tab	200 MG	30	Tablets	30	DAYS				
56483065000340	Filspari	sparsentan tab	400 MG	30	Tablets	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has a diagnosis of primary immunoglobulin A nephropathy (IgAN) confirmed by kidney biopsy **AND** 2. ONE of the following: A. The patient has a urine protein-to-creatinine ratio (UPCR) greater than or equal to 1.5 g/g **OR** B. The patient has proteinuria greater than or equal to 1 g/day **AND** 3. The patient's eGFR is greater than or equal to 30 mL/min/1.73 m^2 **AND** 4. If the patient has an FDA labeled indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. There is support for using the requested agent for the patient's age for the requested indication **AND** 5. ONE of the following A. The patient has tried and had an inadequate response after at least 3 months of therapy with a maximally tolerated angiotensin-converting-enzyme inhibitor (ACEI, e.g., benazepril, lisinopril) or angiotensin II blocker (ARB, e.g., losartan), or a combination medication containing an ACEI or ARB **OR** B. The patient has an intolerance or hypersensitivity to an ACEI or ARB, or a combination medication containing an ACEI or ARB **OR** C. The patient has an FDA labeled contraindication to ALL ACEI or ARB **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL ACEI and ARB cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 6. ONE of the following: A. The patient has tried and had an inadequate response after a 6 month course of glucocorticoid therapy (e.g., methylprednisolone, prednisolone, prednisone) **OR** B. The patient has an intolerance or hypersensitivity to a glucocorticoid **OR** C. The patient has an FDA labeled contraindication to ALL glucocorticoids **OR** D. The prescriber has provided information to support that glucocorticoid therapy is NOT appropriate for the patient **OR** E. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** F. The prescriber has provided documentation that ALL glucocorticoids cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 7. The patient will NOT use the requested agent in combination with an ACEI, ARB, endothelin receptor antagonist (ERA, e.g., bosentan), or aliskiren **AND** 8. The prescriber is a specialist in the area of the patient's diagnosis (e.g., nephrologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 9. The patient does NOT have any FDA labeled contraindications to the requested agent

	Length of Approval: 9 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND** 2. The patient has had improvements or stabilization with the requested agent as indicated by ONE of the following: A. Decrease from baseline (prior to treatment with the requested agent) of urine protein-to-creatinine (UPCR) ratio **OR** B. Decrease from baseline (prior to treatment with the requested agent) in proteinuria **AND** 3. The patient will NOT use the requested agent in combination with an angiotensin-converting-enzyme inhibitor (ACEI, e.g., benazepril, lisinopril), angiotensin II blocker (ARB, e.g., losartan), endothelin receptor antagonist (ERA, e.g., bosentan), or aliskiren **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., nephrologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Universal QL	**Quantity limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: A. BOTH of the following: 1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **OR** B. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 2. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** C. BOTH of the following: 1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **Length of Approval:** up to 12 months

• Program Summary: Hemlibra (emicizumab-kxwh)

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

QUANTITY LIMIT INFORMATION

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Additional QL Information	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
85105030202007	Hemlibra	emicizumab-kxwh subcutaneous soln	12 MG/0.4ML	Determined by patient weight and dosing interval* *See Hemlibra weight based approvable quantities chart for guidance			
85105030202060	Hemlibra	emicizumab-kxwh subcutaneous soln	300 MG/2ML	Determined by patient weight and dosing interval* *See Hemlibra weight based approvable quantities chart for guidance			
85105030202030	Hemlibra	Emicizumab-kxwh Subcutaneous Soln 105 MG/0.7ML (150 MG/ML)	105 MG/0.7ML	Determined by patient weight and dosing interval* *See Hemlibra weight based approvable quantities chart for guidance			
85105030202040	Hemlibra	Emicizumab-kxwh Subcutaneous Soln 150 MG/ML	150 MG/ML	Determined by patient weight and dosing interval* *See Hemlibra weight based approvable quantities chart for guidance			
85105030202010	Hemlibra	Emicizumab-kxwh Subcutaneous Soln 30 MG/ML	30 MG/ML	Determined by patient weight and dosing interval* *See Hemlibra weight based approvable quantities chart for guidance			
85105030202020	Hemlibra	Emicizumab-kxwh Subcutaneous Soln 60 MG/0.4ML (150 MG/ML)	60 MG/0.4ML	Determined by patient weight and dosing interval* *See Hemlibra weight based approvable quantities chart for guidance			

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The requested agent is eligible for continuation of therapy AND ONE of the following: **Agents Eligible for Continuation of Therapy** Hemlibra (emicizumab-kxwh) 1. The patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR** 2. The prescriber states the patient has been treated with the requested agent within the past 90 days (starting on samples is not approvable) AND is at risk if therapy is changed **OR** B. The patient has a diagnosis of hemophilia A with or without inhibitors **AND** 2. The requested agent will be used as prophylaxis to prevent or reduce the frequency of bleeding episodes **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis [e.g., prescriber working in a hemophilia treatment center (HTC), hematologist with hemophilia experience] or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**

4. The patient will NOT be using the requested agent in combination with any of the following while on maintenance dosing with the requested agent:
    A. Prophylaxis with a Factor VIIa product (e.g., NovoSeven RT) **OR**
    B. Prophylaxis with a Factor VIII product (e.g., Advate, Adynovate, Eloctate, Nuwiq, Recombinate, Xyntha) **OR**
    C. Prophylaxis with a bypassing agent (e.g., Feiba, NovoSeven) **OR**
    D. Immune tolerance therapy (ITT) (immune tolerance induction [ITI]) **AND**
5. If the patient is receiving Feiba [activated prothrombin complex concentrate (aPCC)] for breakthrough bleeds, BOTH of the following:
    A. The patient will be monitored for thrombotic microangiopathy and thromboembolism **AND**
    B. The prescriber has counseled the patient on the maximum dosages of Feiba to be used (i.e., no more than 100 u/kg/24 hours) **AND**
6. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**
7. The requested quantity (dose) is within the FDA labeled dosing based on the patient's weight and dosing interval

Length of Approval: 1 month for induction therapy; 12 months for maintenance therapy (or remainder of 12 months if requesting induction therapy and maintenance therapy)

NOTE: If Quantity Limit applies, please see Quantity Limit criteria

Renewal Evaluation

Target Agent(s) will be approved when ALL of the following are met:

1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process (Note: patients not previously approved for the requested agent will require initial evaluation review) **AND**
2. ONE of the following:
    A. The patient has had improvements or stabilization with the requested agent as indicated by number of breakthrough bleeds as reported in the treatment log and/or chart notes (medical records including treatment log and/or chart notes required) **OR**
    B. There is support for the continued use of the requested agent (medical record required) **AND**
3. If the patient is receiving Feiba [activated prothrombin complex concentrate (aPCC)] for breakthrough bleeds, the patient will be monitored for thrombotic microangiopathy and thromboembolism **AND**
4. The prescriber is a specialist in the area of the patient's diagnosis [e.g., prescriber working in a hemophilia treatment center (HTC), hematologist with hemophilia experience] or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**
5. The patient will NOT be using the requested agent in combination with any of the following:
    A. Prophylaxis with a Factor VIIa product (e.g., NovoSeven RT) **OR**
    B. Prophylaxis with a Factor VIII product (e.g., Advate, Adynovate, Eloctate, Nuwiq, Recombinate, Xyntha) **OR**
    C. Prophylaxis with a bypassing agent (e.g., Feiba, NovoSeven) **OR**
    D. Immune tolerance therapy (ITT) (immune tolerance induction [ITI]) **AND**
6. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**
7. The requested quantity (dose) is within the FDA labeled dosing based on the patient's weight and dosing interval

Length of Approval: 12 months

NOTE: If Quantity Limit applies, please see Quantity Limit criteria

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval

Initial Evaluation

Quantity Limit for Target Agent(s) will be approved when ONE of the following is met:

1. The patient is requesting induction therapy only **OR**
2. The patient is requesting induction therapy and maintenance therapy and the requested quantity (dose) for maintenance therapy does not exceed the program quantity limit (see Hemlibra Weight-Based Approvable Quantities chart) **OR**
3. The patient is requesting maintenance therapy only and the requested quantity (dose) does not exceed the program quantity limit (see the Hemlibra Weight-Based Approvable Quantities chart)

Length of Approval: up to 12 months

Renewal Evaluation

Quantity Limit for the Target Agent(s) will be approved when the requested quantity (dose) for maintenance therapy does not exceed the program quantity limit (see the Hemlibra Weight-Based Approvable Quantities chart)

Length of Approval: up to 12 months

Hemlibra Weight-Based Approvable Quantities (maintenance dosing)

Weight (kg)	Dosing Schedule	12 mg/0.4 mL vials	30 mg/1 mL vials	60 mg/0.4 mL vials	105 mg/0.7 mL vials	150 mg/1 mL vials	300 mg/2 mL vial
less than or equal to 5 kg	1.5 mg/kg every week	1.6 mL (4 vials)/28 days	0	0	0	0	0
less than or equal to 5 kg	3 mg/kg every 2 weeks	0	2 mL (2 vials)/28 days	0	0	0	0
less than or equal to 5 kg	6 mg/kg every 4 weeks	0	1 mL (1 vial)/28 days	0	0	0	0
greater than 5 and less than or equal to 10 kg	1.5 mg/kg every week	0	4 mL (4 vials)/28 days	0	0	0	0
greater than 5 and less than or equal to 10 kg	3 mg/kg every 2 weeks	0	2 mL (2 vials)/28 days	0	0	0	0
greater than 5 and less than or equal to 10 kg	6 mg/kg every 4 weeks	0	0	0.4 mL (1 vial)/28 days	0	0	0
greater than 10 and less than or equal to 15 kg	1.5 mg/kg every week	0	4 mL (4 vials)/28 days	0	0	0	0

greater than 10 and less than or equal to 15 kg	3 mg/kg every 2 weeks	0	0	0.8 mL (2 vials)/28 days	0	0	0
greater than 10 and less than or equal to 15 kg	6 mg/kg every 4 weeks	0	1 mL (1 vial)/28 days	0.4 mL (1 vial)/28 days	0	0	0
greater than 15 and less than or equal to 20 kg	1.5 mg/kg every week	0	4 mL (4 vials)/28 days	0	0	0	0
greater than 15 and less than or equal to 20 kg	3 mg/kg every 2 weeks	0	0	0.8 mL (2 vials)/28 days	0	0	0
greater than 15 and less than or equal to 20 kg	6 mg/kg every 4 weeks	0	0	0.8 mL (2 vials)/28 days	0	0	0
greater than 20 and less than or equal to 25 kg	1.5 mg/kg every week	0	0	1.6 mL (4 vials)/28 days	0	0	0
greater than 20 and less than or equal to 25 kg	3 mg/kg every 2 weeks	0	2 mL (2 vials)/28 days	0.8 mL (2 vials)/28 days	0	0	0
greater than 20 and less than or equal to 25 kg	6 mg/kg every 4 weeks	0	0	0	0	1 mL (1 vial)/28 days	0
greater than 25 and less than or equal to 30 kg	1.5 mg/kg once every week	0	0	1.6 mL (4 vials)/28 days	0	0	0
greater than 25 and less than or equal to 30 kg	3 mg/kg every 2 weeks	0	2 mL (2 vials)/28 days	0.8 mL (2 vials)/28 days	0	0	0
greater than 25 and less than or equal to 30 kg	6 mg/kg every 4 weeks	0	0	1.2 mL (3 vials)/28 days	0	0	0
greater than 30 and less than or equal to 35 kg	1.5 mg/kg once every week	0	0	1.6 mL (4 vials)/28 days	0	0	0
greater than 30 and less than or equal to 35 kg	3mg/kg every 2 weeks	0	0	0	1.4 mL (2 vials)/28 days	0	0
greater than 30 and less than or equal to 35 kg	6 mg/kg every 4 weeks	0	0	0	1.4 mL (2 vials)/28 days	0	0
greater than 35 and less than or equal to 40 kg	1.5 mg/kg once every week	0	0	1.6 mL (4 vials)/28 days	0	0	0

greater than 35 and less than or equal to 40 kg	3 mg/kg every 2 weeks	0	0	1.6 mL (4 vials)/28 days	0	0	0
greater than 35 and less than or equal to 40 kg	6 mg/kg every 4 weeks	0	0	1.6 mL (4 vials)/28 days	0	0	0
greater than 40 and less than or equal to 45 kg	1.5 mg/kg once every week	0	4 mL (4 vials)/28 days	1.6 mL (4 vials)/28 days	0	0	0
greater than 40 and less than or equal to 45 kg	3 mg/kg every 2 weeks	0	2 mL (2 vials)/28 days	0	1.4 mL (2 vials)/28 days	0	0
greater than 40 and less than or equal to 45 kg	6 mg/kg every 4 weeks	0	0	0.8 mL (2 vials)/28 days	0	1 mL (1 vial)/28 days	0
greater than 45 and less than or equal to 50 kg	1.5 mg/kg once every week	0	4 mL (4 vials)/28 days	1.6 mL (4 vials)/28 days	0	0	0
greater than 45 and less than or equal to 50 kg	3 mg/kg every 2 weeks	0	0	0	0	2 mL (2 vials)/28 days	0
greater than 45 and less than or equal to 50 kg	6 mg/kg every 4 weeks	0	0	0	0	0	2 mL (1 vial)/28 days
greater than 50 and less than or equal to 55 kg	1.5 mg/kg once every week	0	4 mL (4 vials)/28 days	1.6 mL (4 vials)/28 days	0	0	0
greater than 50 and less than or equal to 55 kg	3 mg/kg every 2 weeks	0	0	0.8 mL (2 vials)/28 days	1.4 mL (2 vials)/28 days	0	0
greater than 50 and less than or equal to 55 kg	6 mg/kg every 4 weeks	0	0	0.8 mL (2 vials)/28 days	1.4 mL (2 vials)/28 days	0	0
greater than 55 and less than or equal to 60 kg	1.5 mg/kg once every week	0	4 mL (4 vials)/28 days	1.6 mL (4 vials)/28 days	0	0	0
greater than 55 and less than or equal to 60 kg	3 mg/kg every 2 weeks	0	0	2.4 mL (6 vials)/28 days	0	0	0
greater than 55 and less than or equal to 60 kg	6 mg/kg every 4 weeks	0	0	0.4 mL (1 vial)/28 days	0	0	2 mL (1 vial/28 days)
greater than 60 and less than or equal to 65 kg	1.5 mg/kg once every week	0	0	0	2.8 mL (4 vials)/28 days	0	0

greater than 60 and less than or equal to 65 kg	3 mg/kg every 2 weeks	0	2 mL (2 vials)/28 days	0.8 mL (2 vials)/28 days	1.4 mL (2 vials)/28 days	0	0
greater than 60 and less than or equal to 65 kg	6 mg/kg every 4 weeks	0	0	1.6 mL (4 vials)/28 days	0	1 mL (1 vial)/28 days	0
greater than 65 and less than or equal to 70 kg	1.5 mg/kg once every week	0	0	0	2.8 mL (4 vials)/28 days	0	0
greater than 65 and less than or equal to 70 kg	3 mg/kg every 2 weeks	0	0	0	2.8 mL (4 vials)/28 days	0	0
greater than 65 and less than or equal to 70 kg	6 mg/kg every 4 weeks	0	0	0.8 mL (2 vials)/28 days	0	0	2 mL (1 vial)/28 days
greater than 70 and less than or equal to 75 kg	1.5 mg/kg once every week	0	0	3.2 mL (8 vials)/28 days	0	0	0
greater than 70 and less than or equal to 75 kg	3 mg/kg every 2 weeks	0	0	1.6mL (4 vials)/28 days	1.4 mL (2 vials)/28 days	0	0
greater than 70 and less than or equal to 75 kg	6 mg/kg every 4 weeks	0	0	0	0	3 mL (3 vials)/28 days	0
greater than 75 and less than or equal to 80 kg	1.5 mg/kg once every week	0	0	3.2 mL (8 vials)/28 days	0	0	0
greater than 75 and less than or equal to 80 kg	3 mg/kg every 2 weeks	0	0	3.2 mL (8 vials)/28 days	0	0	0
greater than 75 and less than or equal to 80 kg	6 mg/kg every 4 weeks	0	0	0.4 mL (1 vial)/28 days	2.8 mL (4 vials)/28 days	0	0
greater than 80 and less than or equal to 85 kg	1.5 mg/kg once every week	0	4 mL (4 vials)/28 days	0	2.8 mL (4 vials)/28 days	0	0
greater than 80 and less than or equal to 85 kg	3 mg/kg every 2 weeks	0	0	0	1.4 mL (2 vials)/28 days	2 mL (2 vials)/28 days	0
greater than 80 and less than or equal to 85 kg	6 mg/kg every 4 weeks	0	0	0.4 mL (1 vial)/28 days	0	3 mL (3 vials)/28 days	0

greater than 85 and less than or equal to 90 kg	1.5 mg/kg once every week	0	4 mL (4 vials)/28 days	0	2.8 mL (4 vials)/28 days	0	0
greater than 85 and less than or equal to 90 kg	3 mg/kg every 2 weeks	0	0	1.6 mL (4 vials)/28 days	0	2 mL (2 vials)/28 days	0
greater than 85 and less than or equal to 90 kg	6 mg/kg every 4 weeks	0	0	0.8 mL (2 vials)/28 days	2.8 mL (4 vials)/28 days	0	0
greater than 90 and less than or equal to 95 kg	1.5 mg/kg once every week	0	0	0	0	4 mL (4 vials)/28 days	0
greater than 90 and less than or equal to 95 kg	3 mg/kg every 2 weeks	0	0	2.4 mL (6 vials)/28 days	1.4 mL (2 vials)/28 days	0	0
greater than 90 and less than or equal to 95 kg	6 mg/kg every 4 weeks	0	0	0	2.8 mL (4 vials)/28 days	1 mL (1 vial)/28 days	0
greater than 95 and less than or equal to 100 kg	1.5 mg/kg once every week	0	0	0	0	4 mL (4 vials)/28 days	0
greater than 95 and less than or equal to 100 kg	3 mg/kg every 2 weeks	0	0	0	0	0	4 mL (2 vials)/28 days
greater than 95 and less than or equal to 100 kg	6 mg/kg every 4 weeks	0	0	0	0	0	4 mL (2 vials)/28 days
greater than 100 and less than or equal to105 kg	1.5 mg/kg once every week	0	0	1.6 mL (4 vials)/28 days	2.8 mL (4 vials)/28 days	0	0
greater than 100 and less than or equal to 105 kg	3 mg/kg every 2 weeks	0	0	0	4.2 mL (6 vials)/28 days	0	0
greater than 100 and less than or equal to 105 kg	6 mg/kg every 4 weeks	0	0	0	4.2 mL (6 vials)/28 days	0	0
greater than 105 and less than or equal to 110 kg	1.5 mg/kg once every week	0	0	1.6 mL (4 vials)/28 days	2.8 mL (4 vials)/28 days	0	0

greater than 105 and less than or equal to 110 kg	3 mg/kg every 2 weeks	0	0	1.6 mL (4 vials)/28 days	2.8 mL (4 vials)/28 days	0	0
greater than 105 and less than or equal to 110 kg	6 mg/kg every 4 weeks	0	0	0.4 mL (1 vial)/28 days	0	0	4 mL (2 vials/28 days)
greater than 110 and less than or equal to 115 kg	1.5 mg/kg once every week	0	0	4.8 mL (12 vials)/28 days	0	0	0
greater than 110 and less than or equal to 115 kg	3 mg/kg every 2 weeks	0	0	3.2 mL (8 vials)/28 days	1.4 mL (2 vials)/28 days	0	0
greater than 110 and less than or equal to 115 kg	6 mg/kg every 4 weeks	0	0	0.4 mL (1 vial)/28 days	4.2 mL (6 vials)/28 days	0	0
greater than 115 and less than or equal to 120 kg	1.5 mg/kg once every week	0	0	4.8 mL (12 vials)/28 days	0	0	0
greater than 115 and ≤less than or equal to120 kg	3 mg/kg every 2 weeks	0	0	0.8 mL (2 vials)/28 days	0	0	4 mL (2 vials)/28 days
greater than 115 and less than or equal to 120 kg	6 mg/kg every 4 weeks	0	0	0.8 mL (2 vials)/28 days	0	0	4 mL (2 vials)/28 days
greater than 120 and less than or equal to 125 kg	1.5 mg/kg once every week	0	4 mL (4 vials)/28 days	1.6 mL (4 vials)/28 days	2.8 mL (4 vials)/28 days	0	0
greater than 120 and less than or equal to 125 kg	3 mg/kg every 2 weeks	0	0	0.8 mL (2 vials)/28 days	4.2 mL (6 vials)/28 days	0	0
greater than 120 and less than or equal to 125 kg	6 mg/kg every 4 weeks	0	0	0	0	5 mL (5 vials)/28 days	0
greater than 125 and less than or equal to130 kg	1.5 mg/kg once every week	0	4 mL (4 vials)/28 days	1.6 mL (4 vials)/28 days	2.8 mL (4 vials)/28 days	0	0
greater than 125 and less than or equal to 130 kg	3 mg/kg every 2 weeks	0	0	3.2 mL (8 vials)/28 days	0	2 mL (2 vials)/28 days	0
greater than 125 and less than or equal to 130 kg	6 mg/kg every 4 weeks	0	0	1.2 mL (3 vials)/28 days	0	0	4 mL (2 vials)/28 days

greater than 130 and less than or equal to 135 kg	1.5 mg/kg once every week	0	0	0	5.6 mL (8 vials)/28 days	0	0
greater than 130 and less than or equal to 135 kg	3 mg/kg every 2 weeks	0	0	0	1.4 mL (2 vials)/28 days	0	4 mL (2 vials)/28 days
greater than 130 and less than or equal to 135 kg	6 mg/kg every 4 weeks	0	0	0.4 mL (1 vial)/28 days	0	5 mL (5 vials)/28 days	0
greater than 135 and less than or equal to 140 kg	1.5 mg/kg once every week	0	0	0	5.6 mL (8 vials)/28 days	0	0
greater than 135 and less than or equal to 140 kg	3 mg/kg every 2 weeks	0	0	1.6 mL (4 vials)/28 days	0	0	4 mL (2 vials)/28 days
greater than 135 and less than or equal to 140 kg	6 mg/kg every 4 weeks	0	0	0	5.6 mL (8 vials)/28 days	0	0
greater than 140 and less than or equal to 145 kg	1.5 mg/kg once every week	0	0	3.2 mL (8 vials)/28 days	2.8 mL (4 vials)/28 days	0	0
greater than 140 and less than or equal to 145 kg	3 mg/kg every 2 weeks	0	0	1.6 mL (4 vials)/28 days	4.2 mL (6 vials)/28 days	0	0
greater than 140 and less than or equal to 145 kg	6 mg/kg every 4 weeks	0	0	0.8 mL (2 vials)/28 days	0	5 mL (5 vials)/28 days	0
greater than 145 and less than or equal to 150 kg	1.5 mg/kg once every week	0	0	3.2 mL (8 vials)/28 days	2.8 mL (4 vials)/28 days	0	0
greater than 145 and less than or equal to 150 kg	3 mg/kg every 2 weeks	0	0	0	0	6 mL (6 vials)/28 days	0
greater than 145 and less than or equal to 150 kg	6 mg/kg every 4 weeks	0	0	0	0	0	6 mL (3 vials)/28 days
greater than 150 and less than or equal to 155 kg	1.5 mg/kg once every week	0	4 mL (4 vials)/28 days	0	5.6 mL (8 vials)/28 days	0	0

greater than 150 and less than or equal to 155 kg	3 mg/kg every 2 weeks	0	0	0.8 mL (2 vials)/28 days	1.4 mL (2 vials)/28 days	0	4 mL (2 vials)/28 days
greater than 150 and less than or equal to 155 kg	6 mg/kg every 4 weeks	0	1 mL (1 vial)/28 days	0	0	0	6 mL (3 vials)/28 days
greater than 155 and less than or equal to 160 kg	1.5 mg/kg once every week	0	4 mL (4 vials)/28 days	0	5.6 mL (8 vials)/28 days	0	0
greater than 155 and less than or equal to 160 kg	3 mg/kg every 2 weeks	0	2 mL (2 vials)/28 days	0	0	6 mL (6 vials)/28 days	0
greater than 155 and less than or equal to 160 kg	6 mg/kg every 4 weeks	0	0	0.4 mL (1 vial)/28 days	0	0	6 mL (3 vials)/28 days
greater than 160 and less than or equal to 165 kg	1.5 mg/kg once every week	0	0	0	2.8 mL (4 vials)/28 days	4 mL (4 vials)/28 days	0
greater than 160 and less than or equal to 165 kg	3 mg/kg every 2 weeks	0	0	2.4 mL (6 vials)/28 days	4.2 mL (6 vials)/28 days	0	0
greater than 160 and less than or equal to 165 kg	6 mg/kg every 4 weeks	0	1 mL (1 vial)/28 days	0	1.4 mL (2 vials)/28 days	5 mL (5 vials)/28 days	0
greater than 165 and less than or equal to 170 kg	1.5 mg/kg once every week	0	0	0	2.8 mL (4 vials)/28 days	4 mL (4 vials)/28 days	0
greater than 165 and less than or equal to 170 kg	3 mg/kg every 2 weeks	0	0	0.8 mL (2 vials)/28 days	0	6 mL (6 vials)/28 days	0
greater than 165 and less than or equal to 170 kg	6 mg/kg every 4 weeks	0	0	0.4 mL (1 vial)/28 days	1.4 mL (2 vials)/28 days	5 mL (5 vials)/28 days	0
greater than 170 and less than or equal to 175 kg	1.5 mg/kg once every week	0	0	2.4 mL (4 vials)/28 days	5.6 mL (8 vials)/28 days	0	0
greater than 170 and less than or equal to 175 kg	3 mg/kg every 2 weeks	0	0	0.8 mL (2 vials)/28 days	4.2 mL (6 vials)/28 days	2 mL (2 vials)/28 days	0

greater than 170 and less than or equal to 175 kg	6 mg/kg every 4 weeks	0	0	0	0	7 mL (7 vials)/28 days	0
greater than 175 and less than or equal to 180 kg	1.5 mg/kg once every week	0	0	2.4 mL (4 vials)/28 days	5.6 mL (8 vials)/28 days	0	0
greater than 175 and less than or equal to 180 kg	3 mg/kg every 2 weeks	0	2 mL (2 vials)/28 days	0	2.8 mL (4 vials)/28 days	0	4 mL (2 vials)/28 days
greater than 175 and less than or equal to 180 kg	6 mg/kg every 4 weeks	0	1 mL (1 vial)/28 days	0	0	7 mL (7 vials)/28 days	0
greater than 180 and less than or equal to 185 kg	1.5 mg/kg once every week	0	4 mL (4 vials)/28 days	0	2.8mL (4 vials)/28 days	4 mL (4 vials)/28 days	0
greater than 180 and less than or equal to 185 kg	3 mg/kg every 2 weeks	0	0	0	1.4 mL (2 vials)/28 days	6 mL (6 vials)/28 days	0
greater than 180 and less than or equal to 185 kg	6 mg/kg every 4 weeks	0	0	0.4 mL (1 vial)/28 days	0	7 mL (7 vials)/28 days	0
greater than 185 and less than or equal to 190 kg	1.5 mg/kg once every week	0	4 mL (4 vials)/28 days	0	2.8mL (4 vials)/28 days	4 mL (4 vials)/28 days	0
greater than 185 and less than or equal to 190 kg	3 mg/kg every 2 weeks	0	0	0.8 mL (2 vials)/28 days	2.8 mL (4 vials)/28 days	0	4 mL (2 vials)/28 days
greater than 185 and less than or equal to 190 kg	6 mg/kg every 4 weeks	0	1 mL (1 vial)/28 days	0	1.4 mL (2 vials)/28 days	0	6 mL (3 vials)/28 days
greater than 190 and less than or equal to 195 kg	1.5 mg/kg once every week	0	0	0	0	0	8 mL (4 vials)/28 days
greater than 190 and less than or equal to 195 kg	3 mg/kg every 2 weeks	0	2 mL (2 vials)/28 days	0	1.4 mL (2 vials)/28 days	6 mL (6 vials)/28 days	0
greater than 190 and less than or equal to 195 kg	6 mg/kg every 4 weeks	0	0	0.4 mL (1 vial)/28 days	1.4 mL (2 vials)/28 days	0	6 mL (3 vials)/28 days
greater than 195 and less than or equal to 200 kg	1.5 mg/kg once every week	0	0	0	0	0	8 mL (4 vials)/28 days

greater than 195 and less than or equal to 200 kg	3 mg/kg every 2 weeks	0	0	0	0	0	8 mL (4 vials)/28 days
greater than 195 and less than or equal to 200 kg	6 mg/kg every 4 weeks	0	0	0	0	0	8 mL (4 vials)/28 days
greater than 200 kg	Approve quantity requested if appropriate for patient weight and dosing interval						

The 12 mg and 30 mg vials are the same concentration (30 mg/mL) and may be combined for dosing

The 60 mg, 105 mg, 150 mg, and/or 300 mg vials are the same concentration (150 mg/mL) and may be combined for dosing

The 12 mg vials and 30 mg vials (30mg/mL) should NOT be combined in the same injection with the 60 mg, 105 mg, 150 mg, or 300 mg vials and should be given as a separate injection

• Program Summary: Hemophilia Factor IX

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Final Module	Target Agent GPI	Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Targeted NDCs When Exclusions Exist	Final Age Limit	Preferred Status	Effective Date
	851000280021	Alphanine sd	coagulation factor ix for inj	1000 UNIT ; 1500 UNIT ; 500 UNIT	M ; N ; O ; Y				
	851000284021	Alprolix	coagulation factor ix (recomb) (rfixfc) for inj	1000 UNIT ; 2000 UNIT ; 250 UNIT ; 3000 UNIT ; 4000 UNIT ; 500 UNIT	M ; N ; O ; Y				
	851000282064	Benefix	coagulation factor ix (recombinant) for inj kit	1000 UNIT ; 2000 UNIT ; 250 UNIT ; 3000 UNIT ; 500 UNIT	M ; N ; O ; Y				
	851000283521	Idelvion	coagulation factor ix (recomb) (rix-fp) for inj	1000 UNIT ; 2000 UNIT ; 250 UNIT ; 3500 UNIT ; 500 UNIT	M ; N ; O ; Y				
	851000282021	Ixinity ; Rixubis	coagulation factor ix (recombinant) for inj	1000 UNIT ; 1500 UNIT ; 2000 UNIT ; 250 UNIT ; 3000 UNIT ; 500 UNIT	M ; N ; O ; Y				
	851000300021	Profilnine	factor ix complex for inj	1000 UNIT ; 1500 UNIT ; 500 UNIT	M ; N ; O ; Y				
	851000284521	Rebinyn	coagulation factor ix recomb glycopegylated for inj	1000 UNIT ; 2000 UNIT ; 3000 UNIT ; 500 UNIT	M ; N ; O ; Y				

ADDITIONAL QUANTITY INFORMATION

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Additional QL Information	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
851000280021	Alphanine sd	coagulation factor ix for inj	1000 UNIT ; 1500 UNIT ; 500 UNIT	Dependent on patient weight and number of doses			
851000284021	Alprolix	coagulation factor ix (recomb) (rfixfc) for inj	1000 UNIT ; 2000 UNIT ; 250 UNIT ; 3000 UNIT ; 4000 UNIT ; 500 UNIT	Dependent on patient weight and number of doses			
851000282064	Benefix	coagulation factor ix (recombinant) for inj kit	1000 UNIT ; 2000 UNIT ; 250 UNIT ; 3000 UNIT ; 500 UNIT	Dependent on patient weight and number of doses			
851000283521	Idelvion	coagulation factor ix (recomb) (rix-fp) for inj	1000 UNIT ; 2000 UNIT ; 250 UNIT ; 3500 UNIT ; 500 UNIT	Dependent on patient weight and number of doses			
851000282021	Ixinity ; Rixubis	coagulation factor ix (recombinant) for inj	1000 UNIT ; 1500 UNIT ; 2000 UNIT ; 250 UNIT ; 3000 UNIT ; 500 UNIT	Dependent on patient weight and number of doses			
851000300021	Profilnine	factor ix complex for inj	1000 UNIT ; 1500 UNIT ; 500 UNIT	Dependent on patient weight and number of doses			
851000284521	Rebinyn	coagulation factor ix recomb glycopegylated for inj	1000 UNIT ; 2000 UNIT ; 3000 UNIT ; 500 UNIT	Dependent on patient weight and number of doses			

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval

Initial Evaluation

Preferred and Non-Preferred Agents to be determined by client

Preferred Agents	Non-Preferred Agents
AlphaNine SD Alprolix BeneFIX Idelvion Ixinity Profilnine Rebinyn Rixubis	

Target Agent(s) will be approved when ALL of the following are met:

1. ONE of the following:
   A. The requested agent is eligible for continuation of therapy AND ONE of the following:

Agents Eligible for Continuation of Therapy
All target agents are eligible for continuation of therapy

   1. The patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR**

2. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR**

B. BOTH of the following:

1. The patient has a diagnosis of hemophilia B (also known as Factor IX deficiency, Christmas disease) AND ONE of the following:

A. The patient is currently experiencing a bleed AND BOTH of the following:

1. The patient is out of medication **AND**
2. The patient needs to receive a ONE TIME emergency supply of medication **OR**

B. BOTH of the following:

1. The requested agent is being used for ONE of the following:

A. Prophylaxis **OR**
B. On-demand use for bleeds **OR**
C. Peri-operative management of bleeding **AND**

2. If the client has preferred agent(s) then ONE of the following:

A. The requested agent is a preferred agent **OR**
B. The patient has tried and had an inadequate response to ALL preferred agent(s) **OR**
C. The patient has an intolerance, or hypersensitivity to ALL of the preferred agent(s) **OR**
D. The patient has an FDA labeled contraindication to ALL of the preferred agent(s) **OR**
E. The patient is currently being treated with the requested agent as indicated by ALL of the following:

1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**

F. The prescriber has provided documentation the preferred agent(s) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**

2. If the patient has an FDA labeled indication, ONE of the following:

A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**
B. There is support for using the requested agent for the patient's age for the requested indication **AND**

2. The prescriber is a specialist in the area of the patient's diagnosis (e.g., prescriber working in a hemophilia treatment center [HTC], hematologist with hemophilia experience) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**
3. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**
4. The prescriber must provide the actual prescribed dose with ALL of the following:
   A. Patient's weight **AND**
   B. Severity of the factor deficiency (i.e., severe is less than 1% factor activity, moderate is greater than or equal to 1 to less than or equal to 5% factor activity, mild is greater than5 to 40% factor activity) **AND**
   C. Inhibitor status **AND**
   D. Intended use/regimen: prophylaxis, on-demand, peri-operative **AND**
5. ONE of the following:

	A. The patient will NOT be using the requested agent in combination with another Factor IX agent included in this program **OR** B. There is support for the use of more than one unique Factor IX agent (medical records required) **Length of Approval:** One time emergency use: up to 2 weeks, Peri-operative dosing: 1 time per request, On-demand: up to 3 months, Prophylaxis: up to 12 months Note: If Quantity Limit applies, please see Quantity Limit criteria **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process (if current request is for a ONE TIME emergency use or the patient ONLY has previous approvals for emergency use, must use Initial Evaluation) (Note: patients not previously approved for the requested agent will require initial evaluation review) **AND** 2. The prescriber is a specialist in the area of the patient's diagnosis (e.g., prescriber working in a hemophilia treatment center [HTC], hematologist with hemophilia experience) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 4. The prescriber must provide the actual prescribed dose with ALL of the following: A. Patient's weight **AND** B. Severity of the factor deficiency (i.e., severe is less than 1% factor activity, moderate is greater than or equal to 1 to less than or equal to 5% factor activity, mild is greater than 5 to 40% factor activity) **AND** C. Inhibitor status **AND** D. Intended use/regimen: (e.g., prophylaxis, on-demand, peri-operative) **AND** 5. ONE of the following: A. The prescriber communicated with the patient (via any means) regarding the frequency and severity of the patient's bleeds and has verified that the patient does not have greater than 5 on-demand doses on hand **OR** B. There is support for the patient having more than 5 on-demand doses on hand **AND** 6. ONE of the following: A. The patient will NOT be using the requested agent in combination with another Factor IX agent included in this program **OR** B. There is support for the use of more than one unique Factor IX agent (medical records required) **Length of Approval:** On-demand: up to 3 months, Peri-operative dosing: 1 time per request, Prophylaxis: up to 12 months NOTE: If Quantity Limit applies, please see Quantity Limit criteria

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity Limit for the requested agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit defined by BOTH of the following: A. The requested quantity (dose) is within the FDA labeled dosing **AND** B. The requested quantity (number of doses) is appropriate based on intended use (e.g., prophylaxis, on-demand, peri-operative) **OR**

	2. There is support for exceeding the defined program quantity limit (dose and number of doses) (medical records required) **Length of Approval:** For initial one-time emergency use: up to 2 weeks Prophylaxis: up to 12 months Both initial and renewal Peri-operative dosing: 1 time per request Both initial and renewal On-demand: up to 3 months

• Program Summary: Hyperpolarization-Activated Cyclic Nucleotide-Gated (HCN) Channel Blocker (Corlanor)

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Corlanor	Ivabradine HCl Oral Soln 5 MG/5ML (Base Equiv)	5 MG/5ML	600	mL	30	DAYS			
Corlanor	Ivabradine HCl Tab 5 MG (Base Equiv)	5 MG	60	Tablets	30	DAYS			
Corlanor	Ivabradine HCl Tab 7.5 MG (Base Equiv)	7.5 MG	60	Tablets	30	DAYS			

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
PA	**Initial Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The requested agent is eligible for continuation of therapy AND ONE of the following: **Agents Eligible for Continuation of Therapy** All target agents are eligible for continuation of therapy 1. The patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR** 2. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR** B. The patient has a diagnosis of stable symptomatic heart failure (NYHA Class II-IV) due to dilated cardiomyopathy (DCM) AND BOTH of the following: 1. The patient is in sinus rhythm **AND** 2. The patient has an elevated heart rate **OR** C. The patient has a diagnosis of stable symptomatic chronic heart failure (NYHA Class II-IV) AND ALL of the following: 1. The patient has a left ventricular ejection fraction (LVEF) less than or equal to 35% **AND**

	2. The patient is in sinus rhythm **AND** 3. The patient has a resting heart rate of greater than or equal to 70 beats per minute **AND** 4. ONE of the following: A. BOTH of the following: 1. The patient is currently treated with a maximally tolerated beta blocker **AND** 2. The patient will continue beta blocker therapy **OR** B. The patient has an intolerance, hypersensitivity, or FDA labeled contraindication to beta blocker therapy **OR** D. The patient has another FDA labeled indication for the requested agent and route of administration **OR** E. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND** 2. If the patient has an FDA labeled indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. There is support for using the requested agent for the patient's age for the requested indication **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS or DrugDex 1 or 2a level of evidence **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL with PA	**Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: A. BOTH of the following: 1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **OR** B. BOTH of the following:

	1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 2. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** C. BOTH of the following: 1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **Length of approval:** up to 12 months

• Program Summary: Interleukin-13 (IL-13) Antagonist

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
9027308045E520	Adbry	Tralokinumab-ldrm Subcutaneous Soln Prefilled Syr	150 MG/ML	4	Syringes	28	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The requested agent is eligible for continuation of therapy AND ONE of the following: **Agents Eligible for Continuation of Therapy** All target agents are eligible for continuation of therapy 1. The patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR** 2. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR** B. BOTH of the following: 1. ONE of the following: A. The patient has a diagnosis of moderate-to-severe atopic dermatitis (AD) AND ALL of the following: 1. ONE of the following: A. The patient has at least 10% body surface area involvement **OR** B. The patient has involvement of body sites that are difficult to treat with prolonged topical corticosteroid therapy (e.g., hands, feet, face, neck, scalp, genitals/groin, skin folds) **OR**

C. The patient has an Eczema Area and Severity Index (EASI) score greater than or equal to 16 **OR**
D. The patient has an Investigator Global Assessment (IGA) score greater than or equal to 3 **AND**

2. ONE of the following:
   A. The patient has tried and had an inadequate response to at least a medium-potency topical corticosteroid used in the treatment of AD **OR**
   B. The patient has an intolerance or hypersensitivity to at least a medium-potency topical corticosteroid used in the treatment of AD **OR**
   C. The patient has an FDA labeled contraindication to ALL medium-, high-, and super-potency topical steroids used in the treatment of AD **OR**
   D. The patient is currently being treated with the requested agent as indicated by ALL of the following:
      1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
      2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on the requested agent **AND**
      3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
   E. The prescriber has provided documentation that ALL medium-, high-, and super-potency topical steroids used in the treatment of AD cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**
3. ONE of the following:
   A. The patient has tried and had an inadequate response to a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) used in the treatment of AD **OR**
   B. The patient has an intolerance or hypersensitivity to a topical calcineurin inhibitor used in the treatment of AD **OR**
   C. The patient has an FDA labeled contraindication to ALL topical calcineurin inhibitors used in the treatment of AD **OR**
   D. The patient is currently being treated with the requested agent as indicated by ALL of the following:
      1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
      2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on the requested agent **AND**
      3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
   E. The prescriber has provided documentation that ALL topical calcineurin inhibitors used in the treatment of AD cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**
4. The prescriber has documented the patient's baseline (prior to therapy with the requested agent) pruritus and other symptom severity (e.g., erythema,

edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification) **OR**

B. The patient has another FDA labeled indication for the requested agent and route of administration **AND**

2. If the patient has an FDA labeled indication, then ONE of the following:
   A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**
   B. There is support for using the requested agent for the patient's age for the requested indication **OR**

C. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND**

2. If the patient has a diagnosis of moderate-to-severe atopic dermatitis (AD), then BOTH of the following:
   A. The patient is currently treated with topical emollients and practicing good skin care **AND**
   B. The patient will continue the use of topical emollients and good skin care practices in combination with the requested agent **AND**
3. ONE of the following:
   A. The patient is initiating therapy with the requested agent **OR**
   B. The patient has been treated with the requested agent for less than 16 consecutive weeks **OR**
   C. The patient has been treated with the requested agent for at least 16 consecutive weeks AND ONE of the following:
      1. The patient weighs less than 100 kg and ONE of the following:
         A. The patient has achieved clear or almost clear skin AND the patient's dose will be reduced to 300 mg every 4 weeks **OR**
         B. The patient has NOT achieved clear or almost clear skin **OR**
         C. There is support for therapy using 300 mg every 2 weeks **OR**
      2. The patient weighs greater than or equal to 100 kg **AND**
4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist, allergist, immunologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**
5. ONE of the following (please refer to "Agents NOT to be used Concomitantly" table):
   A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR**
   B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following:
      1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND**
      2. There is support for the use of combination therapy (submitted copy of clinical trials, phase III studies, guidelines required) **AND**
6. The patient does NOT have any FDA labeled contraindications to the requested agent

Compendia Allowed: AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use

Length of Approval: 6 months

Note: Initial loading dose is allowed for Adbry and may require a Quantity Limit review. The loading dose plus maintenance dose may be approved for 1 month, followed by maintenance dosing for the remainder of the length of approval.

NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

Renewal Evaluation

Target Agent(s) will be approved when ALL of the following are met:

	1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND** 2. ONE of the following: A. The patient has a diagnosis of moderate-to-severe atopic dermatitis AND BOTH of the following: 1. The patient has had a reduction or stabilization from baseline (prior to therapy with the requested agent) of ONE of the following: A. Affected body surface area **OR** B. Flares **OR** C. Pruritus, erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification **OR** D. A decrease in the Eczema Area and Severity Index (EASI) score **OR** E. A decrease in the Investigator Global Assessment (IGA) score **AND** 2. The patient will continue standard maintenance therapies (e.g., topical emollients, good skin care practices) in combination with the requested agent **OR** B. The patient has a diagnosis other than moderate-to-severe atopic dermatitis AND has had clinical benefit with the requested agent **AND** 3. ONE of the following: A. The patient is initiating therapy with the requested agent **OR** B. The patient has been treated with the requested agent for less than 16 consecutive weeks **OR** C. The patient has been treated with the requested agent for at least 16 consecutive weeks AND ONE of the following: 1. The patient weighs less than 100 kg and ONE of the following: A. The patient has achieved clear or almost clear skin AND the patient's dose will be reduced to 300 mg every 4 weeks **OR** B. The patient has NOT achieved clear or almost clear skin **OR** C. There is support for therapy using 300 mg every 2 weeks **OR** 2. The patient weighs greater than or equal to 100 kg **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist, allergist, immunologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 5. ONE of the following (please refer to "Agents NOT to be used Concomitantly" table): A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** 2. There is support for the use of combination therapy (submitted copy of clinical trials, phase III studies, guidelines required) **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed**: AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **Length of Approval**: 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity limit for the Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR**

	2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: A. BOTH of the following: 1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **OR** B. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 2. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **Length of Approval:** up to 12 months Note: If approving initial loading dose for Adbry, approve quantity for loading dose plus maintenance for 1 month followed by maintenance dose for the remainder of the length of approval. Maintenance dosing begins 2 weeks after patient receives the loading dose.

CONTRAINDICATION AGENTS

Contraindicated as Concomitant Therapy
Agents NOT to be used Concomitantly Abrilada (adalimumab-afzb) Actemra (tocilizumab) Adalimumab Adbry (tralokinumab-ldrm) Amjevita (adalimumab-atto) Arcalyst (rilonacept) Avsola (infliximab-axxq) Benlysta (belimumab) Bimzelx (bimekizumab-bkzx) Cibinqo (abrocitinib) Cimzia (certolizumab) Cinqair (reslizumab) Cosentyx (secukinumab) Cyltezo (adalimumab-adbm) Dupixent (dupilumab) Enbrel (etanercept) Entyvio (vedolizumab) Fasenra (benralizumab) Hadlima (adalimumab-bwwd) Hulio (adalimumab-fkjp) Humira (adalimumab) Hyrimoz (adalimumab-adaz) Idacio (adalimumab-aacf) Ilaris (canakinumab) Ilumya (tildrakizumab-asmn) Inflectra (infliximab-dyyb) Infliximab Kevzara (sarilumab) Kineret (anakinra) Litfulo (ritlecitinib) Nucala (mepolizumab) Olumiant (baricitinib) Omvoh (mirikizumab-mrkz)

Contraindicated as Concomitant Therapy
Opzelura (ruxolitinib)
Orencia (abatacept)
Otezla (apremilast)
Remicade (infliximab)
Renflexis (infliximab-abda)
Riabni (rituximab-arrx)
Rinvoq (upadacitinib)
Rituxan (rituximab)
Rituxan Hycela (rituximab/hyaluronidase human)
Ruxience (rituximab-pvvr)
Siliq (brodalumab)
Simlandi (adalimumab-ryvk)
Simponi (golimumab)
Simponi ARIA (golimumab)
Skyrizi (risankizumab-rzaa)
Sotyktu (deucravacitinib)
Spevigo (spesolimab-sbzo)
Stelara (ustekinumab)
Taltz (ixekizumab)
Tezspire (tezepelumab-ekko)
Tofidence (tocilizumab-bavi)
Tremfya (guselkumab)
Truxima (rituximab-abbs)
Tyenne (tocilizumab-aazg)
Tysabri (natalizumab)
Velsipity (etrasimod)
Wezlana (ustekinumab-auub)
Xeljanz (tofacitinib)
Xeljanz XR (tofacitinib extended release)
Xolair (omalizumab)
Yuflyma (adalimumab-aaty)
Yusimry (adalimumab-aqvh)
Zeposia (ozanimod)
Zymfentra (infliximab-dyyb)

• Program Summary: Ocaliva (obeticholic acid)

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
52750060000330	Ocaliva	Obeticholic Acid Tab 10 MG	10 MG	30	Tablets	30	DAYS				
52750060000320	Ocaliva	Obeticholic Acid Tab 5 MG	5 MG	30	Tablets	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation

Target Agent(s) will be approved when ALL of the following are met:

1. ONE of the following:
    A. The patient has a diagnosis of primary biliary cholangitis (PBC) and ALL of the following:
        1. Diagnosis was confirmed by at least TWO of the following:
            A. There is biochemical evidence of cholestasis with an alkaline phosphatase (ALP) elevation
            B. Presence of antimitochondrial antibody (AMA): a titer greater than 1:80
            C. If the AMA is negative or present only in low titer (less than or equal to 1:80), presence of other PBC-specific autoantibodies, including sp100 or gp210
            D. Histologic evidence of nonsuppurative destruction cholangitis and destruction of interlobular bile ducts **AND**
        2. The prescriber has measured the patient's baseline alkaline phosphatase (ALP) level and total bilirubin level (prior to therapy with the requested agent) **AND**
        3. ONE of the following:
            A. The patient does NOT have cirrhosis **OR**
            B. The patient has compensated cirrhosis with NO evidence of portal hypertension **AND**
        4. ONE of the following:
            A. BOTH of the following:
                1. The patient has tried and had an inadequate response after at least 1 year of therapy with ursodeoxycholic acid (UDCA) (inadequate response defined as ALP greater than normal, and/or total bilirubin greater than the upper limit of normal [ULN] but less than 2x ULN, after 1 year of treatment with UDCA) **AND**
                2. The patient will continue treatment with ursodeoxycholic acid (UDCA) with the requested agent **OR**
            B. The patient has an intolerance or hypersensitivity to therapy with ursodeoxycholic acid (UDCA) **OR**
            C. The patient has an FDA labeled contraindication to ursodeoxycholic acid (UDCA) **OR**
    B. The patient has another FDA labeled indication for the requested agent **AND**
2. If the patient has an FDA labeled indication, then ONE of the following:
    A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**
    B. There is support for using the requested agent for the patient's age for the requested indication **AND**
3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterologist, hepatologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**
4. The patient does NOT have any FDA labeled contraindications to the requested agent

Length of Approval: 12 months

NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

Renewal Evaluation

Target Agent(s) will be approved when ALL of the following are met:

1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND**
2. ONE of the following:
    A. The patient has a diagnosis of primary biliary cholangitis (PBC) and ALL of the following:
        1. ONE of the following:
            A. The patient does NOT have cirrhosis **OR**

	B. The patient has compensated cirrhosis with NO evidence of portal hypertension **AND** 2. ONE of the following: A. The requested agent will be used in combination with ursodeoxycholic acid (UDCA) **OR** B. The patient has an intolerance or hypersensitivity to therapy with ursodeoxycholic acid (UDCA) **OR** C. The patient has an FDA labeled contraindication to ursodeoxycholic acid (UDCA) **AND** 3. The patient has had an alkaline phosphatase (ALP) decrease of greater than or equal to 15% from baseline (prior to therapy with the requested agent) AND ALP is less than normal **AND** 4. The patient's total bilirubin is less than or equal to the upper limit of normal (ULN) **OR** B. The patient has another FDA labeled indication AND the patient has had clinical benefit with the requested agent **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., gastroenterologist, hepatologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval**: 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity limit for the Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: A. BOTH of the following: 1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **OR** B. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 2. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** C. BOTH of the following: 1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **Length of Approval:** up to 12 months

• Program Summary: Ophthalmic Pilocarpine

Applies to:	☑ Commercial Formularies
Type:	☐ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
86501030102017	Vuity	Pilocarpine HCl Ophth Soln	1.25 %	5	mL	30	DAYS				

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL	**Quantity limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: A. BOTH of the following: 1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **OR** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **OR** C. BOTH of the following: 1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **Length of Approval**: up to 12 months

• Program Summary: Oral Anticoagulant

Applies to:	☑ Commercial Formularies
Type:	☐ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
83370010000320	Eliquis	Apixaban Tab 2.5 MG	2.5 MG	60	Tablets	30	DAYS				
83370010000330	Eliquis	Apixaban Tab 5 MG	5 MG	74	Tablets	30	DAYS				
8337001000B720	Eliquis starter pack	Apixaban Tab Starter Pack	5 MG	1	Pack	180	DAYS				
83337030200130	Pradaxa	Dabigatran Etexilate Mesylate Cap 110 MG (Etexilate Base Eq)	110 MG	120	Capsules	30	DAYS				
83337030200140	Pradaxa	Dabigatran Etexilate Mesylate Cap 150 MG (Etexilate Base Eq)	150 MG	60	Capsules	30	DAYS				
83337030200120	Pradaxa	Dabigatran Etexilate Mesylate Cap 75 MG (Etexilate Base Eq)	75 MG	60	Capsules	30	DAYS				
83337030203020	Pradaxa	dabigatran etexilate mesylate pellet pack	20 MG	60	Packets	30	DAYS				
83337030203025	Pradaxa	dabigatran etexilate mesylate pellet pack	30 MG	120	Packets	30	DAYS				
83337030203030	Pradaxa	dabigatran etexilate mesylate pellet pack	40 MG	120	Packets	30	DAYS				
83337030203035	Pradaxa	dabigatran etexilate mesylate pellet pack	50 MG	120	Packets	30	DAYS				
83337030203040	Pradaxa	dabigatran etexilate mesylate pellet pack	110 MG	120	Packets	30	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
83337030203045	Pradaxa	dabigatran etexilate mesylate pellet pack	150 MG	60	Packets	30	DAYS				
833700302003	Savaysa	edoxaban tosylate tab	15 MG ; 30 MG ; 60 MG	30	Tablets	30	DAYS				
83370060001920	Xarelto	Rivaroxaban For Susp	1 MG/ML	4	Bottles	30	DAYS				
83370060000320	Xarelto	Rivaroxaban Tab 10 MG	10 MG	30	Tablets	30	DAYS				
83370060000330	Xarelto	Rivaroxaban Tab 15 MG	15 MG	60	Tablets	30	DAYS				
83370060000310	Xarelto	Rivaroxaban Tab 2.5 MG	2.5 MG	60	Tablets	30	DAYS				
83370060000340	Xarelto	Rivaroxaban Tab 20 MG	20 MG	30	Tablets	30	DAYS				
8337006000B720	Xarelto starter pack	Rivaroxaban Tab Starter Therapy Pack 15 MG & 20 MG	15 & 20 MG	1	Pack	30	DAYS				

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Eliquis and Savaysa	**Quantity limit for the Target Agent(s)** will be approved when ONE of the following is met 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: A. BOTH of the following: 1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **OR** B. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 2. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** C. BOTH of the following: 1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **Length of Approval**: 12 months or as requested by the prescriber, whichever is shorter
Pradaxa	**Quantity limit for the Target Agent(s)** will be approved when ONE of the following is met 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The indicated use is prophylaxis of DVT and PE in an adult patient who has undergone hip replacement surgery **AND** the prescriber has provided information in support of therapy with a higher quantity (duration) for the requested indication **OR** 3. The indicated use is to reduce the risk of stroke and systemic embolism in an adult patient with nonvalvular atrial fibrillation OR treatment of DVT and PE OR reduction in the risk of recurrence of DVT and PE **AND** BOTH of the following: A. The requested dosage form is NOT 110 mg **AND** B. ONE of the following: 1. BOTH of the following:

	i. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** ii. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** 2. BOTH of the following: i. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** ii. There is support for therapy with a higher dose for the requested indication **OR** 4. The indicated use is other than those listed above **AND** there is support for therapy with a higher quantity (dose) for the requested indication **Length of Approval**: 12 months or as requested by the prescriber, whichever is shorter
Xarelto	**Quantity limit for the Target Agent(s)** will be approved when ONE of the following is met 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The indicated use is prophylaxis of DVT which may lead to PE in a patient undergoing hip or knee replacement surgery **AND** the prescriber has provided information in support of therapy with a higher quantity (duration) for the requested indication **OR** 3. The indicated use is reduction of risk of stroke and systemic embolism in a patient with nonvalvular atrial fibrillation OR treatment of DVT/PE **AND** ONE of the following: A. BOTH of the following: i. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** ii. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** B. BOTH of the following: i. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** ii. There is support for therapy with a higher dose for the requested indication **OR** 4. The indicated use is other than those listed above **AND** there is support for therapy with a higher quantity (dose) for the requested indication **Length of Approval:** 12 months or as requested by the prescriber, whichever is shorter

• Program Summary: Otezla (apremilast)

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
6670001500	Otezla	apremilast tab ; apremilast tab starter therapy pack	10 & 20 & 30 MG ; 30 MG	60	Tablets	30	DAYS				
66700015000330	Otezla	Apremilast Tab 30 MG	30 MG	60	Tablets	30	DAYS				
6670001500B720	Otezla	Apremilast Tab Starter Therapy Pack 10 MG & 20 MG & 30 MG	10 & 20 & 30 MG	1	Kit	180	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
PA	**Initial Evaluation** **Target Agent(s)** will be approved when the ALL of the following are met: 1. ONE of the following: A. The requested agent is eligible for continuation of therapy AND ONE of the following: **Agents Eligible for Continuation of Therapy** All target agents are eligible for continuation of therapy 1. The patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR** 2. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR** B. BOTH of the following: 1. ONE of the following: A. The patient has a diagnosis of active psoriatic arthritis (PsA) AND ONE of the following: 1. The patient has tried and had an inadequate response to ONE conventional agent (i.e., cyclosporine, leflunomide, methotrexate, sulfasalazine) used in the treatment of PsA for at least 3-months **OR** 2. The patient has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of PsA **OR** 3. The patient has an FDA labeled contraindication to ALL of the conventional agents used in the treatment of PsA **OR** 4. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of PsA **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL conventional agents (i.e., cyclosporine, leflunomide, methotrexate, sulfasalazine) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** B. The patient has a diagnosis of plaque psoriasis (PS) AND BOTH of the following: 1. ONE of the following: A. The patient is an adult with mild to severe plaque psoriasis **OR** B. The patient is a pediatric patient 6 years of age or older AND BOTH of the following: 1. The patient has moderate to severe plaque psoriasis **AND** 2. The patient weighs at least 20 kg **AND** 2. ONE of the following:

A. The patient has tried and had an inadequate response to ONE conventional agent (i.e., acitretin, anthralin, calcipotriene, calcitriol, coal tar products, cyclosporine, methotrexate, pimecrolimus, PUVA [phototherapy], tacrolimus, tazarotene, topical corticosteroids) used in the treatment of PS for at least 3-months **OR**
B. The patient has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of PS **OR**
C. The patient has an FDA labeled contraindication to ALL conventional agents used in the treatment of PS **OR**
D. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of PS **OR**
E. The patient is currently being treated with the requested agent as indicated by ALL of the following:
    1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
    2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
    3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
F. The prescriber has provided documentation that ALL conventional agents (i.e., acitretin, anthralin, calcipotriene, calcitriol, coal tar products, cyclosporine, methotrexate, pimecrolimus, PUVA [phototherapy], tacrolimus, tazarotene, topical corticosteroids) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR**

C. The patient has a diagnosis of Behcet's disease (BD) AND ALL of the following:
    1. The patient has active oral ulcers associated with BD **AND**
    2. The patient has had at least 3 occurrences of oral ulcers in the last 12-months **AND**
    3. ONE of the following:
        A. The patient has tried and had an inadequate response to ONE conventional agent (i.e., topical oral corticosteroids [i.e., triamcinolone dental paste], colchicine, azathioprine) used in the treatment of BD **OR**
        B. The patient has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of BD **OR**
        C. The patient has an FDA labeled contraindication to ALL conventional agents used in the treatment of BD **OR**
        D. The patient's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of BD **OR**
        E. The patient is currently being treated with the requested agent as indicated by ALL of the following:
            1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
            2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
            3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**

F. The prescriber has provided documentation that ALL conventional agents (i.e., topical oral corticosteroids [i.e., triamcinolone dental paste], colchicine, azathioprine) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR**

D. The patient has another FDA labeled indication for the requested agent not mentioned previously **AND**

2. If the patient has an FDA labeled indication, then ONE of the following:
   A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**
   B. There is support for using the requested agent for the patient's age for the requested indication **OR**

C. The patient has another indication that is supported in compendia for the requested agent not mentioned previously **AND**

2. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table):
   A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR**
   B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following:
      1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND**
      2. There is support for the use of combination therapy (copy of support required, e.g., clinical trials, phase III studies, guidelines) **AND**
3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist, rheumatologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**
4. The patient does NOT have any FDA labeled contraindications to the requested agent

Compendia Allowed: AHFS or DrugDex 1 or 2a level of evidence

Length of approval: 12 months

NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

Renewal Evaluation

Target Agent(s) will be approved when ALL of the following are met:

1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND**
2. The patient has had clinical benefit with the requested agent **AND**
3. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table):
   A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR**
   B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following:
      1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND**
      2. There is support for the use of combination therapy (copy of support required, e.g., clinical trials, phase III studies, guidelines) **AND**

	4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist, rheumatologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL with PA	**Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit **OR** 3. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** C. There is support of therapy with a higher dose for the requested indication (e.g., clinical trials, phase III studies, guidelines required) **Length of Approval**: up to 12 months

CONTRAINDICATION AGENTS

Contraindicated as Concomitant Therapy
Agents NOT to be used Concomitantly
Abrilada (adalimumab-afzb)
Actemra (tocilizumab)
Adalimumab
Adbry (tralokinumab-ldrm)
Amjevita (adalimumab-atto)
Arcalyst (rilonacept)
Avsola (infliximab-axxq)
Benlysta (belimumab)
Bimzelx (bimekizumab-bkzx)
Cibinqo (abrocitinib)
Cimzia (certolizumab)
Cinqair (reslizumab)
Cosentyx (secukinumab)
Cyltezo (adalimumab-adbm)
Dupixent (dupilumab)
Enbrel (etanercept)
Entyvio (vedolizumab)
Fasenra (benralizumab)
Hadlima (adalimumab-bwwd)
Hulio (adalimumab-fkjp)
Humira (adalimumab)

Contraindicated as Concomitant Therapy
Hyrimoz (adalimumab-adaz)
Idacio (adalimumab-aacf)
Ilaris (canakinumab)
Ilumya (tildrakizumab-asmn)
Inflectra (infliximab-dyyb)
Infliximab
Kevzara (sarilumab)
Kineret (anakinra)
Litfulo (ritlecitinib)
Nucala (mepolizumab)
Olumiant (baricitinib)
Omvoh (mirikizumab-mrkz)
Opzelura (ruxolitinib)
Orencia (abatacept)
Otezla (apremilast)
Remicade (infliximab)
Renflexis (infliximab-abda)
Riabni (rituximab-arrx)
Rinvoq (upadacitinib)
Rituxan (rituximab)
Rituxan Hycela (rituximab/hyaluronidase human)
Ruxience (rituximab-pvvr)
Siliq (brodalumab)
Simlandi (adalimumab-ryvk)
Simponi (golimumab)
Simponi ARIA (golimumab)
Skyrizi (risankizumab-rzaa)
Sotyktu (deucravacitinib)
Spevigo (spesolimab-sbzo)
Stelara (ustekinumab)
Taltz (ixekizumab)
Tezspire (tezepelumab-ekko)
Tofidence (tocilizumab-bavi)
Tremfya (guselkumab)
Truxima (rituximab-abbs)
Tyenne (tocilizumab-aazg)
Tysabri (natalizumab)
Velsipity (etrasimod)
Wezlana (ustekinumab-auub)
Xeljanz (tofacitinib)
Xeljanz XR (tofacitinib extended release)
Xolair (omalizumab)
Yuflyma (adalimumab-aaty)
Yusimry (adalimumab-aqvh)
Zeposia (ozanimod)

• Program Summary: Sunosi (solriamfetol)

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
61370070200340	Sunosi	Solriamfetol HCl Tab 150 MG (Base Equiv)	150 MG	30	Tablets	30	DAYS				
61370070200320	Sunosi	Solriamfetol HCl Tab 75 MG (Base Equiv)	75 MG	30	Tablets	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The patient has a diagnosis of excessive daytime sleepiness associated with obstructive sleep apnea (OSA) AND ALL of the following: 1. The underlying airway obstruction has been treated (e.g., continuous positive airway pressure [CPAP]) for at least 1-month prior to initiating therapy with the requested agent **AND** 2. The modalities to treat the underlying airway obstruction (e.g., continuous positive airway pressure [CPAP]) will be continued during treatment with the requested agent **AND** 3. ONE of the following: A. The patient has tried and had an inadequate response to armodafinil OR modafinil **OR** B. The patient has an intolerance or hypersensitivity to armodafinil OR modafinil **OR** C. The patient has an FDA labeled contraindication to BOTH armodafinil AND modafinil **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that BOTH armodafinil AND modafinil cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** B. The patient has a diagnosis of excessive daytime sleepiness associated with narcolepsy AND ONE of the following: 1. The patient has tried and had an inadequate response to armodafinil OR modafinil **OR** 2. The patient has an intolerance or hypersensitivity to armodafinil OR modafinil **OR** 3. The patient has an FDA labeled contraindication to BOTH armodafinil AND modafinil **OR** 4. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND**

	B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 5. The prescriber has provided documentation that BOTH armodafinil AND modafinil cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist, psychiatrist, pulmonologist, sleep disorder specialist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months Note: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. If the diagnosis is excessive daytime sleepiness associated with obstructive sleep apnea (OSA), the modalities to treat the underlying airway obstruction (e.g., continuous positive airway pressure [CPAP]) will be continued during treatment with the requested agent **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., neurologist, psychiatrist, pulmonologist, sleep disorder specialist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months Note: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL	**Quantity limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: A. BOTH of the following: 1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication **AND**

	2. There is support for therapy with a higher dose for the requested indication **OR** B. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 2. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit **OR** C. BOTH of the following: 1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **Length of Approval:** up to 12 months

• Program Summary: Thrombopoietin Receptor Agonists and Tavalisse

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
82405030050310	Alvaiz	eltrombopag choline tab	9 MG	30	Tablets	30	DAYS				
82405030050320	Alvaiz	eltrombopag choline tab	18 MG	30	Tablets	30	DAYS				
82405030050330	Alvaiz	eltrombopag choline tab	36 MG	60	Tablets	30	DAYS				
82405030050340	Alvaiz	eltrombopag choline tab	54 MG	60	Tablets	30	DAYS				
82405010200320	Doptelet	Avatrombopag Maleate Tab 20 MG (Base Equiv)	20 MG	60	Tablets	30	DAYS				
82405045000320	Mulpleta	Lusutrombopag Tab 3 MG	3 MG	7	Tablets	7	DAYS				
82405030103030	Promacta	Eltrombopag Olamine Powder Pack for Susp 12.5 MG (Base Eq)	12.5 MG	30	Packets	30	DAYS				
82405030103020	Promacta	Eltrombopag Olamine Powder Pack for Susp 25 MG (Base Equiv)	25 MG	30	Packets	30	DAYS				
82405030100310	Promacta	Eltrombopag Olamine Tab 12.5 MG (Base Equiv)	12.5 MG	30	Tablets	30	DAYS				
82405030100320	Promacta	Eltrombopag Olamine Tab 25 MG (Base Equiv)	25 MG	30	Tablets	30	DAYS				
82405030100330	Promacta	Eltrombopag Olamine Tab 50 MG (Base Equiv)	50 MG	60	Tablets	30	DAYS				
82405030100340	Promacta	Eltrombopag Olamine Tab 75 MG (Base Equiv)	75 MG	60	Tablets	30	DAYS				
857560401003	Tavalisse	fostamatinib disodium tab	100 MG ; 150 MG	60	Tablets	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation

Target Agent(s) will be approved when the ALL of the following are met:

1. ONE of the following:
    A. The requested agent is Doptelet AND ONE of the following:
        1. The patient has a diagnosis of chronic (defined as lasting for at least 12 months) immune (idiopathic) thrombocytopenia (ITP) AND BOTH of the following:
            A. ONE of the following:
                1. The patient has a platelet count less than or equal to 30 X 10^9/L **OR**
                2. The patient has a platelet count greater than 30 X 10^9/L but less than 50 X 10^9/L AND has symptomatic bleeding and/or an increased risk for bleeding **AND**
            B. ONE of the following:
                1. The patient has tried and had an inadequate response to ONE corticosteroid used for the treatment of ITP **OR**
                2. The patient has an intolerance or hypersensitivity to ONE corticosteroid used for the treatment of ITP **OR**
                3. The patient has an FDA labeled contraindication to ALL corticosteroids used for the treatment of ITP **OR**
                4. The patient has tried and had an inadequate response to another thrombopoietin receptor agonist (e.g., Nplate, Promacta) or Tavalisse **OR**
                5. The patient has tried and had an inadequate response to immunoglobulins (IVIg or Anti-D) **OR**
                6. The patient has had an inadequate response to a splenectomy **OR**
                7. The patient has tried and had an inadequate response to rituximab **OR**
                8. The patient is currently being treated with the requested agent as indicated by ALL of the following:
                    A. A statement by the prescriber that the patient is currently taking the requested agent **AND**
                    B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
                    C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
                9. The prescriber has provided documentation that corticosteroids cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR**
        2. The patient has a diagnosis of thrombocytopenia and has chronic liver disease AND ALL of the following:
            A. The patient has a platelet count less than 50 X 10^9/L **AND**
            B. The patient is scheduled to undergo a procedure with an associated risk of bleeding (e.g., gastrointestinal endoscopy, liver biopsy, bronchoscopy, dental procedure) **AND**
            C. The patient would require a platelet transfusion unless platelet counts are clinically increased from baseline (prior to therapy with the requested agent) **OR**
        3. The patient has another FDA labeled indication for the requested agent **OR**
        4. The patient has another indication that is supported in compendia for the requested agent and route of administration **OR**
    B. The requested agent is Mulpleta (lusutrombopag) AND ONE of the following:
        1. The patient has a diagnosis of thrombocytopenia and has chronic liver disease AND ALL of the following:
            A. The patient has a platelet count less than 50 X 10^9/L **AND**
            B. The patient is scheduled to undergo a procedure with an associated risk of bleeding (e.g., gastrointestinal endoscopy, liver biopsy, bronchoscopy, dental procedure) **AND**

C. The patient would require a platelet transfusion unless platelet counts are clinically increased from baseline (prior to therapy with the requested agent) **OR**

2. The patient has another FDA labeled indication for the requested agent **OR**
3. The patient has another indication that is supported in compendia for the requested agent and route of administration **OR**

C. The requested agent is Nplate (romiplostim) AND ONE of the following:

1. The patient has a diagnosis of hematopoietic syndrome of acute radiation syndrome (HS-ARS) **OR**
2. The patient has a diagnosis of immune (idiopathic) thrombocytopenia (ITP) AND ALL of the following:
   A. If the patient is a pediatric patient, then the patient has had ITP for at least 6 months **AND**
   B. ONE of the following:
      1. The patient has a platelet count less than or equal to 30 X 10^9/L **OR**
      2. The patient has a platelet count greater than 30 X 10^9/L but less than 50 x 10^9/L AND has symptomatic bleeding and/or an increased risk for bleeding **AND**
   C. ONE of the following:
      1. The patient has tried and had an inadequate response to ONE corticosteroid used for the treatment of ITP **OR**
      2. The patient has an intolerance or hypersensitivity to ONE corticosteroid used for the treatment of ITP **OR**
      3. The patient has an FDA labeled contraindication to ALL corticosteroids used for the treatment of ITP **OR**
      4. The patient has tried and had an inadequate response to immunoglobulins (IVIg or anti-D) **OR**
      5. The patient has had an inadequate response to a splenectomy **OR**
      6. The patient has tried and had an inadequate response to rituximab **OR**
      7. The patient is currently being treated with the requested agent as indicated by ALL of the following:
         A. A statement by the prescriber that the patient is currently taking the requested agent **AND**
         B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
         C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
      8. The prescriber has provided documentation that corticosteroids cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR**
3. The patient has another FDA labeled indication for the requested agent **OR**
4. The patient has another indication that is supported in compendia for the requested agent and route of administration **OR**

D. The requested agent is Promacta (eltrombopag) or Alvaiz AND ONE of the following:

1. The patient has a diagnosis of hepatitis C associated thrombocytopenia AND ONE of the following:
   A. The intent of therapy with the requested agent is to increase platelet counts sufficiently to initiate interferon therapy AND the patient's platelet count is less than 75 x 10^9/L **OR**
   B. The patient is on concomitant therapy with interferon AND is at risk for discontinuing hepatitis C therapy due to thrombocytopenia **OR**
2. The patient has a diagnosis of severe aplastic anemia AND ALL of the following:
   A. The patient has at least 2 of the following blood criteria:

1. Neutrophils less than 0.5 X 10^9/L
2. Platelets less than 30 X 10^9/L
3. Reticulocyte count less than 60 X 10^9/L **AND**

B. The patient has 1 of the following marrow criteria:
1. Severe hypocellularity: less than 25% **OR**
2. Moderate hypocellularity, 25-50% with hematopoietic cells representing less than 30% of residual cells **AND**

C. ONE of the following:
1. BOTH of the following:
A. The patient will use the requested agent as first-line treatment **AND**
B. The patient will use the requested agent in combination with standard immunosuppressive therapy (i.e., antithymocyte globulin [ATG] AND cyclosporine) **OR**
2. ONE of the following:
A. The patient has tried and had an inadequate response to BOTH antithymocyte globulin (ATG) AND cyclosporine therapy **OR**
B. The patient has an intolerance or hypersensitivity to BOTH ATG AND cyclosporine **OR**
C. The patient has an FDA labeled contraindication to BOTH ATG AND cyclosporine **OR**
D. The patient is currently being treated with the requested agent as indicated by ALL of the following:
1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
E. The prescriber has provided documentation that BOTH antithymocyte globulin (ATG) AND cyclosporine therapy cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR**

3. The patient has a diagnosis of persistent or chronic (defined as lasting for at least 3 months) immune (idiopathic) thrombocytopenia (ITP) AND BOTH of the following:
A. ONE of the following:
1. The patient has a platelet count less than or equal to 30 x 10^9/L **OR**
2. The patient has a platelet count greater than 30 x 10^9/L but less than 50 x 10^9/L AND has symptomatic bleeding and/or an increased risk for bleeding **AND**

B. ONE of the following:
1. The patient has tried and had an inadequate response to ONE corticosteroid used for the treatment of ITP **OR**
2. The patient has an intolerance or hypersensitivity to ONE corticosteroid used for the treatment of ITP **OR**
3. The patient has an FDA labeled contraindication to ALL corticosteroids used for the treatment of ITP **OR**
4. The patient has tried and had an inadequate response to immunoglobulins (IVIg or anti-D) **OR**
5. The patient has had an inadequate response to a splenectomy **OR**
6. The patient has tried and had an inadequate response to rituximab **OR**

7. The patient is currently being treated with the requested agent as indicated by ALL of the following:
    A. A statement by the prescriber that the patient is currently taking the requested agent **AND**
    B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
    C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
8. The prescriber has provided documentation that corticosteroids cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR**

4. The patient has another FDA labeled indication for the requested agent **OR**
5. The patient has another indication that is supported in compendia for the requested agent and route of administration **OR**

E. The requested agent is Alvaiz (eltrombopag) AND ONE of the following:
1. The patient has a diagnosis of hepatitis C associated thrombocytopenia AND ONE of the following:
    A. The intent of therapy with the requested agent is to increase platelet counts sufficiently to initiate interferon therapy AND the patient's platelet count is less than 75 x 10^9/L **OR**
    B. The patient is on concomitant therapy with interferon AND is at risk for discontinuing hepatitis C therapy due to thrombocytopenia **OR**
2. The patient has a diagnosis of severe aplastic anemia AND ALL of the following:
    A. The patient has at least 2 of the following blood criteria:
        1. Neutrophils less than 0.5 X 10^9/L
        2. Platelets less than 30 X 10^9/L
        3. Reticulocyte count less than 60 X 10^9/L **AND**
    B. The patient has 1 of the following marrow criteria:
        1. Severe hypocellularity: less than 25% **OR**
        2. Moderate hypocellularity, 25-50% with hematopoietic cells representing less than 30% of residual cells **AND**
    C. ONE of the following:
        1. The patient has tried and had an inadequate response to BOTH antithymocyte globulin (ATG) AND cyclosporine therapy **OR**
        2. The patient has an intolerance or hypersensitivity to BOTH ATG AND cyclosporine **OR**
        3. The patient has an FDA labeled contraindication to BOTH ATG AND cyclosporine **OR**
3. The patient has a diagnosis of persistent or chronic (defined as lasting for at least 3 months) immune (idiopathic) thrombocytopenia (ITP) AND BOTH of the following:
    A. ONE of the following:
        1. The patient has a platelet count less than or equal to 30 x 10^9/L **OR**
        2. The patient has a platelet count greater than 30 x 10^9/L but less than 50 x 10^9/L AND has symptomatic bleeding and/or an increased risk for bleeding **AND**
    B. ONE of the following:
        1. The patient has tried and had an inadequate response to ONE corticosteroid used for the treatment of ITP **OR**
        2. The patient has an intolerance or hypersensitivity to ONE corticosteroid used for the treatment of ITP **OR**
        3. The patient has an FDA labeled contraindication to ALL corticosteroids used for the treatment of ITP **OR**

4. The patient has tried and had an inadequate response to immunoglobulins (IVIg or anti-D) **OR**
5. The patient has had an inadequate response to a splenectomy **OR**
6. The patient has tried and had an inadequate response to rituximab **OR**
7. The patient is currently being treated with the requested agent as indicated by ALL of the following:
    A. A statement by the prescriber that the patient is currently taking the requested agent **AND**
    B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
    C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
8. The prescriber has provided documentation that corticosteroids cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR**

4. The patient has another FDA labeled indication for the requested agent **OR**
5. The patient has another indication that is supported in compendia for the requested agent and route of administration **OR**

F. The requested agent is Tavalisse (fostamatinib disodium hexahydrate) AND ONE of the following:
1. The patient has a diagnosis of chronic (defined as lasting for at least 12 months) immune (idiopathic) thrombocytopenia (ITP) AND BOTH of the following:
    A. ONE of the following:
        1. The patient has a platelet count less than or equal to 30 X 10^9/L **OR**
        2. The patient has a platelet count greater than 30 X 10^9/L but less than 50 x 10^9/L AND has symptomatic bleeding and/or an increased risk for bleeding **AND**
    B. ONE of the following:
        1. The patient has tried and had an inadequate response to ONE corticosteroid used for the treatment of ITP **OR**
        2. The patient has an intolerance or hypersensitivity to ONE corticosteroid used for the treatment of ITP **OR**
        3. The patient has an FDA labeled contraindication to ALL corticosteroids used for the treatment of ITP **OR**
        4. The patient has tried and had an inadequate response to a thrombopoietin receptor agonist (e.g., Doptelet, Nplate, Promacta) **OR**
        5. The patient has tried and had an inadequate response to immunoglobulins (IVIg or Anti-D) **OR**
        6. The patient has had an inadequate response to a splenectomy **OR**
        7. The patient has tried and had an inadequate response to rituximab **OR**
        8. The patient is currently being treated with the requested agent as indicated by ALL of the following:
            A. A statement by the prescriber that the patient is currently taking the requested agent **AND**
            B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
            C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
        9. The prescriber has provided documentation that corticosteroids cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR**

2. The patient has another FDA labeled indication for the requested agent **OR**
3. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND**

2. If the patient has an FDA labeled indication, then ONE of the following:
   A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**
   B. There is support for using the requested agent for the patient's age for the requested indication **AND**
3. ONE of the following:
   A. The patient will NOT be using the requested agent in combination with another agent included in this program **OR**
   B. The patient will use the requested agent in combination with another agent included in this program AND BOTH of the following:
      1. The requested agent is Nplate **AND**
      2. The patient has a diagnosis of hematopoietic syndrome of acute radiation syndrome (HS-ARS) **AND**
4. The patient does NOT have any FDA labeled contraindications to the requested agent

Compendia Allowed: AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use

Lengths of Approval:
Doptelet: thrombocytopenia in patients with chronic liver disease who are scheduled to undergo a procedure - 1 month; all other indications - 6 months
Mulpleta: thrombocytopenia in patients with chronic liver disease who are scheduled to undergo a procedure - 1 month; all other indications - 6 months
Nplate: HS-ARS - 1 time; ITP - 4 months; all other indications - 6 months
Promacta: ITP - 2 months; thrombocytopenia in hep C - 3 months; first-line therapy in severe aplastic anemia - 6 months; all other severe aplastic anemia - 4 months; all other indications - 6 months
Alvaiz: ITP - 2 months; thrombocytopenia in hep C - 3 months; all other severe aplastic anemia - 4 months; all other indications - 6 months
Tavalisse: all indications - 6 months

NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria

Renewal Evaluation

Target Agent(s) will be approved when ALL of the following are met:

1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process. [Note: patients not previously approved for the requested agent will require initial evaluation review] (Note: Doptelet and Mulpleta for thrombocytopenia with chronic liver disease AND Nplate for hematopoietic syndrome of acute radiation syndrome (HS-ARS) should always be reviewed under initial criteria.) **AND**
2. ONE of the following:
   A. The patient has a diagnosis of immune (idiopathic) thrombocytopenia (ITP) AND ONE of the following:
      1. The patient's platelet count is greater than or equal to 50 x 10^9/L **OR**
      2. The patient's platelet count has increased sufficiently to avoid clinically significant bleeding **OR**
   B. The patient has the diagnosis of hepatitis C associated thrombocytopenia AND BOTH of the following:
      1. The patient will be initiating or maintaining hepatitis C therapy with interferon **AND**
      2. ONE of the following:
         A. The patient's platelet count is greater than or equal to 90 x 10^9/L **OR**
         B. The patient's platelet count has increased sufficiently to initiate or maintain interferon therapy for the treatment of hepatitis C **OR**
   C. The patient has a diagnosis other than ITP or hepatitis C associated thrombocytopenia AND has shown clinical improvement with the requested agent **AND**

	3. The patient will NOT be using the requested agent in combination with another agent included in this program **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Lengths of Approval:** thrombocytopenia in hepatitis C - 6 months; all other indications - 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Universal QL	**Quantity limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: A. BOTH of the following: 1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **OR** B. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 2. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** C. BOTH of the following: 1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **Initial Lengths of Approval:** **Doptelet:** thrombocytopenia in patients with chronic liver disease who are scheduled to undergo a procedure - 1 month; all other indications - up to 6 months **Mulpleta:** thrombocytopenia in patients with chronic liver disease who are scheduled to undergo a procedure - 1 month; all other indications - up to 6 months **Nplate:** HS-ARS - 1 time; ITP - up to 4 months; all other indications - up to 6 months **Promacta:** ITP - up to 2 months; thrombocytopenia in hep C - up to 3 months; first-line therapy in severe aplastic anemia - up to 6 months; all other severe aplastic anemia - up to 4 months; all other indications - up to 6 months **Alvaiz:** ITP - 2 months; thrombocytopenia in hep C - 3 months; all other severe aplastic anemia - 4 months; all other indications - 6 months **Tavalisse:** all indications - up to 6 months **Renewal Lengths of Approval:** thrombocytopenia in hepatitis C - up to 6 months; all other indications - up to 12 months

• Program Summary: Vascepa

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
39500035100110	Vascepa	Icosapent Ethyl Cap 0.5 GM	0.5 GM	240	Capsules	30	DAYS				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
39500035100120	Vascepa	Icosapent Ethyl Cap 1 GM	1 GM	120	Capsules	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
PA	

Target Agent(s)	Preferred Target Agent(s)
icosapent ethyl*	Vascepa

*generic available

Initial Evaluation

Target Agent(s) will be approved when ALL of the following are met:

1. ONE of the following:
   - A. The patient has a diagnosis of severe hypertriglyceridemia (fasting triglyceride level of greater than or equal to 500 mg/dL) **OR**
   - B. The patient is using the requested agent to reduce the risk of myocardial infarction, stroke, coronary revascularization, or unstable angina requiring hospitalization AND ALL of the following:
     1. ONE of the following:
        - A. The patient is on maximally tolerated statin therapy **OR**
        - B. The patient has an intolerance or hypersensitivity to statin therapy **OR**
        - C. The patient has an FDA labeled contraindication to ALL statins **AND**
     2. The patient has a fasting triglyceride level of greater than or equal to 135 mg/dL **AND**
     3. ONE of the following:
        - A. The patient has established cardiovascular disease **OR**
        - B. The patient has diabetes mellitus AND 2 or more additional risk factors for cardiovascular disease **OR**
   - C. The patient has another FDA labeled indication for the requested agent and route of administration **OR**
   - D. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND**
2. If the patient has an FDA labeled indication, then ONE of the following:
   - A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**
   - B. There is support for using the requested agent for the patient's age for the requested indication **AND**
3. If the client has preferred agent(s), then ONE of the following:
   - A. The requested agent is a preferred agent **OR**
   - B. The patient has an intolerance or hypersensitivity to the preferred agent(s) that is not expected to occur with the non-preferred agent **OR**
   - C. The patient has an FDA labeled contraindication to the preferred agent(s) that is not expected to occur with the non-preferred agent **OR**
   - D. The patient's medication history includes use of a preferred agent **OR**
   - E. BOTH of the following:
     1. The prescriber has stated that the patient has tried a preferred agent **AND**
     2. The preferred agent was discontinued due to lack of effectiveness or an adverse event **OR**
   - F. The patient is currently being treated with the requested agent as indicated by ALL of the following:
     1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
     2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
     3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
   - G. The prescriber has provided documentation that the preferred agent cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction,

	decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS or DrugDex 1 or 2a level of evidence **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. If the client has preferred agent(s), then ONE of the following: A. The requested agent is a preferred agent **OR** B. The patient has an intolerance or hypersensitivity to the preferred agent(s) that is not expected to occur with the non-preferred agent **OR** C. The patient has an FDA labeled contraindication to the preferred agent(s) that is not expected to occur with the non-preferred agent **OR** D. The patient's medication history includes use of a preferred agent **OR** E. BOTH of the following: 1. The prescriber has stated that the patient has tried a preferred agent **AND** 2. The preferred agent was discontinued due to lack of effectiveness or an adverse event **OR** F. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** G. The prescriber has provided documentation that the preferred agent cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL with PA	**Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: A. BOTH of the following: 1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication **AND**

	2. There is support for therapy with a higher dose for the requested indication **OR** B. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 2. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** C. BOTH of the following: 1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **Length of Approval:** up to 12 months

• Program Summary: Verquvo

Applies to:	☑ Commercial Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ Coverage / Formulary Exception

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Age Limit	Effective Date	Term Date
40900085000321	Verquvo	Vericiguat Tab	2.5 MG	30	Tablets	30	DAYS				
40900085000330	Verquvo	Vericiguat Tab	5 MG	30	Tablets	30	DAYS				
40900085000340	Verquvo	Vericiguat Tab	10 MG	30	Tablets	30	DAYS				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
PA	**Initial Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The requested agent is eligible for continuation of therapy AND ONE of the following: **Agents Eligible for Continuation of Therapy** All target agents are eligible for continuation of therapy 1. The patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR** 2. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR** B. The patient has a diagnosis of symptomatic chronic heart failure (NYHA Class II-IV) and ALL of the following: 1. The patient has a left ventricular ejection fraction (LVEF) less than 45% **AND** 2. ONE of the following: A. Hospitalization of heart failure within the past 6 months **OR** B. Use of outpatient IV diuretics for heart failure within the past 3 months **OR** C. The patient has another FDA labeled indication for the requested agent and route of administration **OR**

	D. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND** 2. If the patient has an FDA labeled indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. There is support for using the requested agent for the patient's age for the requested indication **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS or DrugDex 1 or 2a level of evidence NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Length of Approval:** 12 months **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Length of Approval:** 12 months

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL with PA	**Quantity Limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: A. BOTH of the following: 1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **OR** B. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 2. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** C. BOTH of the following: 1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **Length of Approval**: up to 12 months