MHCP PHARMACY PROGRAM POLICY ACTIVITY

Provider Notification

Policies Effective: September 1, 2024 Notification Posted: August 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:	☑ Medicaid Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ 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			01-01-2022	12-31-9999

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
	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:	☑ Medicaid Formularies
Type:	☐ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ 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	Capsules	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				
12109903300320	Atripla	Efavirenz-Emtricitabine-Tenofovir DF Tab 600-200-300 MG	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				
12109902500320	Combivir	Lamivudine-Zidovudine Tab 150-300 MG	150-300 MG	60	Tablets	30	DAYS				
12109903400320	Complera	Emtricitabine-Rilpivirine-Tenofovir DF Tab 200-25-300 MG	200-25-300 MG	30	Tablets	30	DAYS				
12109903270320	Delstrigo	Doravirine-Lamivudine-Tenofovir DF Tab 100-300-300 MG	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				
12109902260320	Dovato	Dolutegravir Sodium-Lamivudine Tab 50-300 MG (Base Eq)	50-300 MG	30	Tablets	30	DAYS				
12109080100320	Edurant	Rilpivirine HCl Tab 25 MG (Base Equivalent)	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
12106030000120	Emtriva	Emtricitabine Caps 200 MG	200 MG	30	Capsules	30	DAYS				
12106030002010	Emtriva	Emtricitabine Soln 10 MG/ML	10 MG/ML	680	mL	28	DAYS				
12106060002020	Epivir	Lamivudine Oral Soln 10 MG/ML	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				
12109902200340	Epzicom	Abacavir Sulfate-Lamivudine Tab 600-300 MG	600-300 MG	30	Tablets	30	DAYS				
12109902220330	Evotaz	Atazanavir Sulfate-Cobicistat Tab 300-150 MG (Base Equiv)	300-150 MG	30	Tablets	30	DAYS				
12102530002120	Fuzeon	Enfuvirtide For Inj 90 MG	90 MG	60	Vials	30	DAYS				
12109904290315	Genvoya	Elvitegrav-Cobic-Emtricitab-Tenofov AF Tab 150-150-200-10 MG	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				
12109902280320	Juluca	Dolutegravir Sodium-Rilpivirine HCl Tab 50-25 MG (Base Eq)	50-25 MG	30	Tablets	30	DAYS				
12109902552020	Kaletra	Lopinavir-Ritonavir Soln 400-100 MG/5ML (80-20 MG/ML)	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	120	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
		200-50 MG									
12104525101820	Lexiva	Fosamprenavir Calcium Susp 50 MG/ML (Base Equiv)	50 MG/ML	1800	mLs	30	DAYS				
12104525100330	Lexiva	Fosamprenavir Calcium Tab 700 MG (Base Equiv)	700 MG	120	Tablets	30	DAYS				
12104560002020	Norvir	Ritonavir Oral Soln 80 MG/ML	80 MG/ML	480	mLs	30	DAYS				
12104560003020	Norvir	Ritonavir Powder Packet 100 MG	100 MG	360	Packets	30	DAYS				
12104560000320	Norvir	Ritonavir Tab 100 MG	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				
12109025000320	Pifeltro	Doravirine Tab 100 MG	100 MG	30	Tablets	30	DAYS				
12109902270320	Prezcobix	Darunavir-Cobicistat Tab 800-150 MG	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				
12102330407420	Rukobia	Fostemsavir Tromethamine Tab ER 12HR 600 MG	600 MG	60	Tablets	60	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	150-150-200-300	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
		Tab 150-150-200-300 MG	MG								
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				
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				
12109903200320	Trizivir	Abacavir Sulfate-Lamivudine-Zidovudine Tab 300-150-300 MG	300-150-300 MG	60	Tablets	30	DAYS				
12109902300308	Truvada	Emtricitabine-Tenofovir Disoproxil Fumarate Tab 100-150 MG	100-150 MG	30	Tablets	30	DAYS				
12109902300312	Truvada	Emtricitabine-Tenofovir Disoproxil Fumarate Tab 133-200 MG	133-200 MG	30	Tablets	30	DAYS				
12109902300316	Truvada	Emtricitabine-Tenofovir Disoproxil Fumarate Tab 167-250 MG	167-250 MG	30	Tablets	30	DAYS				
12109902300320	Truvada	Emtricitabine-Tenofovir	200-300	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
		Disoproxil Fumarate Tab 200-300 MG	MG								
12109530000320	Tybost	Cobicistat Tab 150 MG	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				
12108570102920	Viread	Tenofovir Disoproxil Fumarate Oral Powder 40 MG/GM	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				
12105005100320	Ziagen	Abacavir Sulfate Tab 300 MG (Base Equiv)	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:	☑ Medicaid Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ 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
	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's medication history includes use of a statin AND ONE of the following: 1. The statin was discontinued due to lack of effectiveness or an adverse event **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over a 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**

Module	Clinical Criteria for Approval
	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:** CMS Approved Compendia **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:** CMS Approved Compendia **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:	☑ Medicaid Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ 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

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's medication history includes at least a medium-potency topical corticosteroid used in the treatment of AD AND ONE of the following:
                  1. The patient has had an inadequate response to medium-potency topical corticosteroids used in the treatment of AD **OR**
                  2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over medium-potency topical

corticosteroids 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 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's medication history includes a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) used in the treatment of AD AND ONE of the following:
        1. The patient has had an inadequate response to a topical calcineurin inhibitors (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) used in the treatment of AD **OR**
        2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over topical calcineurin inhibitors (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 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: CMS Approved Compendia

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**: CMS Approved Compendia **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

CONTRAINDICATION AGENTS

Contraindicated as Concomitant Therapy
Agents NOT to be used Concomitantly Abrilada (adalimumab-afzb) Actemra (tocilizumab) Adalimumab

Contraindicated as Concomitant Therapy
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)
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)

Contraindicated as Concomitant Therapy
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: Egrifta (tesamorelin)

Applies to:	☑ Medicaid Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ 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

Module	Clinical Criteria for Approval
	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:	☑ Medicaid Formularies
Type:	☑ Prior Authorization ☐ Quantity Limit ☐ Step Therapy ☐ 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's medication history includes amitriptyline, cimetidine, or hydroxyzine AND ONE of the following: 1. The patient has had an inadequate response to amitriptyline, cimetidine, or hydroxyzine **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over amitriptyline, cimetidine, and 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: Filspari (sparsentan)

Applies to:	☑ Medicaid Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ 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. BOTH of the following: 1. The patient's medication history includes at least 3 months of therapy with 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 as indicated by ONE of the following: A. Evidence of a paid claim(s) **OR** B. The prescriber has stated that the patient has tried at least 3 months of therapy with 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 **AND** 2. ONE of the following: A. The ACEI or ARB was discontinued due to lack of effectiveness or an adverse event **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL ACEI or ARB medications **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 medications 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**

Module	Clinical Criteria for Approval
	6. ONE of the following: A. BOTH of the following: 1. The patient has tried and had an inadequate response after a 6 month course of glucocorticoid therapy (e.g., methylprednisolone, prednisolone, prednisone) as indicated by ONE of the following: A. Evidence of a paid claim(s) **OR** B. The prescriber has stated that the patient has tried at least 3 months of therapy with maximally tolerated angiotensin-converting-enzyme inhibitor (ACEI, e.g., benazepril, lisinopril) or angiotensin II blocker (ARB, e.g., losartan), or a combination medication containing a glucocorticoid **AND** 2. ONE of the following: A. The glucocorticoid was discontinued due to lack of effectiveness or an adverse event **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL glucocorticoids **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**

Module	Clinical Criteria for Approval
	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
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: Hemlibra

Applies to:	☑ Medicaid Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ 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
	851050302020	Hemlibra	emicizumab-kxwh subcutaneous soln	105 MG/0.7ML ; 12 MG/0.4ML ; 150 MG/ML ; 30 MG/ML ; 300 MG/2ML ; 60 MG/0.4ML	M ; N ; O ; Y				

ADDITIONAL 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			

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Additional QL Information	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
				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

Module	Clinical Criteria for Approval
	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

Module	Clinical Criteria for Approval							
	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

Module	Clinical Criteria for Approval							
	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

Module	Clinical Criteria for Approval							
	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

Module	Clinical Criteria for Approval							
	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

Module	Clinical Criteria for Approval							
	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

Module	Clinical Criteria for Approval							
	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

Module	Clinical Criteria for Approval							
	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

Module	Clinical Criteria for Approval							
	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 Agents

Applies to:	☑ Medicaid Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ 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
	851000102521	Advate ; Kovaltry	antihemophilic factor recomb (rahf-pfm) for inj	1000 UNIT ; 1500 UNIT ; 2000 UNIT ; 250 UNIT ; 3000 UNIT ; 4000 UNIT ; 500 UNIT	M ; N ; O ; Y				
	851000104021	Adynovate	antihemophilic factor recomb pegylated for inj	1000 UNIT ; 1500 UNIT ; 2000 UNIT ; 250 UNIT ; 3000 UNIT ; 500 UNIT ; 750 UNIT	M ; N ; O ; Y				
	851000105564	Afstyla	antihemophilic fact rcmb single chain for inj kit	1000 UNIT ; 1500 UNIT ; 2000 UNIT ; 250 UNIT ; 2500 UNIT ; 3000 UNIT ; 500 UNIT	M ; N ; O ; Y				
	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	M ; N ; O ; Y				
	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				
	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	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				
	851000310021	Coagadex	coagulation factor x	250 UNIT ; 500 UNIT	M ; N ; O ; Y				

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
			(human) for inj						
	851000330064	Corifact	factor xiii concentrate (human) for inj kit	1000 -1600 UNIT	M ; N ; O ; Y				
	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	M ; N ; O ; Y				
	851000103521	Esperoct	antihemophilic factor recomb glycopeg-exei for inj	1000 UNIT ; 1500 UNIT ; 2000 UNIT ; 3000 UNIT ; 500 UNIT	M ; N ; O ; Y				
	851000200021	Feiba	antiinhibitor coagulant complex for iv soln	1000 UNIT ; 2500 UNIT ; 500 UNIT	M ; N ; O ; Y				
	851000100021	Hemofil m ; Koate ; Koate-dvi	antihemophilic factor (human) for inj	1000 UNIT ; 1700 UNIT ; 250 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				
	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	M ; N ; O ; Y				
	851000102064	Kogenate fs	antihemophilic factor recomb (rfviii) for inj kit	1000 UNIT ; 2000 UNIT ; 250 UNIT ; 3000 UNIT ; 500 UNIT	M ; N ; O ; Y				
	851000103321	Novoeight	antihemophilic fact rcmb (bd trunc-rfviii) for inj	1000 UNIT ; 1500 UNIT ; 2000 UNIT ; 250 UNIT ; 3000 UNIT ; 500 UNIT	M ; N ; O ; Y				
	851000262021	Novoseven rt	coagulation factor viia (recomb) for inj	1 MG ; 2 MG ; 5 MG ; 8 MG	M ; N ; O ; Y				
	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	M ; N ; O ; Y				
	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	M ; N ; O ; Y				
	851000105021	Obizur	antihemophilic factor (recomb porc)	500 UNIT	M ; N ; O ; Y				

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
			rpfviii for inj						
	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				
	851000102021	Recombinate	antihemophilic factor recomb (rfviii) for inj	1241 -1800 UNIT ; 1801 -2400 UNIT ; 220 -400 UNIT ; 401 -800 UNIT ; 801 -1240 UNIT	M ; N ; O ; Y				
	851000264021	Sevenfact	coagulation factor viia (recom)-jncw for inj	1 MG ; 5 MG	M ; N ; O ; Y				
	851000321021	Tretten	coagulation factor xiii a-subunit for inj	2500 UNIT	M ; N ; O ; Y				
	851000702021	Vonvendi	von willebrand factor (recombinant) for inj	1300 UNIT ; 650 UNIT	M ; N ; O ; Y				
	851000151064	Wilate	antihemophilic factor/vwf (human) for inj	1000-1000 UNIT ; 500-500 UNIT	M ; N ; O ; Y				
	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	M ; N ; O ; Y				

ADDITIONAL 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
Target Agent(s) EXCEPT Coagadex, NovoSeven RT, and Sevenfact							
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			
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 ;	antihemophilic factor/vwf	1000 UNIT ; 1000-2400	Dependent on patient			

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Additional QL Information	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
	Humate-p	(human) for inj	UNIT ; 1500 UNIT ; 2000 UNIT ; 250 UNIT ; 250-600 UNIT ; 500 UNIT ; 500-1200 UNIT	weight and number of doses			
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			
851000310021	Coagadex	coagulation factor x (human) for inj	250 UNIT ; 500 UNIT	Dependent on patient weight and number of doses			
851000330064	Corifact	factor xiii concentrate (human) for inj kit	1000 -1600 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			
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			
851000200021	Feiba	antiinhibitor coagulant complex for iv soln	1000 UNIT ; 2500 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			
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			
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			
851000262021	Novoseven rt	coagulation factor viia (recomb) for inj	1 MG ; 2 MG ; 5 MG ; 8 MG	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
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			
851000105021	Obizur	antihemophilic factor (recomb porc) rpfviii for inj	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			
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			
851000264021	Sevenfact	coagulation factor viia (recom)-jncw for inj	1 MG ; 5 MG	Dependent on patient weight and number of doses			
851000321021	Tretten	coagulation factor xiii a-subunit for inj	2500 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
Coagadex	**Coagadex** will be approved when ALL of the following are met: 1. ONE of the following: A. The patient has been treated with the requested agent for the requested use (e.g., prophylaxis, on-demand) within the past 90 days **OR** B. The prescriber states the patient has been treated with the requested agent for the requested use (e.g., prophylaxis, on-demand) within the past 90 days AND is at risk if therapy is changed **OR** C. The patient has a diagnosis of hereditary Factor X deficiency 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**

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	2. The requested agent will be used for prophylaxis treatment AND ONE of the following: A. The patient has severe or moderate Factor X deficiency (Factor X level ≤ 5%) **OR** B. The patient has mild Factor X deficiency (Factor X level 6-10%) AND there is support for prophylaxis use of the requested agent (medical records required) **OR** 3. The requested agent will be used as on-demand treatment to control bleeding episodes AND BOTH of the following: A. The prescriber has communicated with the patient (via any means) and has verified that the patient does NOT have more than 5 on-demand doses on hand **AND** B. ONE of the following: 1. The patient's medication history includes aminocaproic acid or tranexamic acid used for the requested indication AND ONE of the following: A. The patient has had an inadequate response to aminocaproic acid or tranexamic acid used for the requested indication **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent aminocaproic acid or tranexamic acid used for the requested indication **OR** 2. The patient has an intolerance or hypersensitivity to aminocaproic acid or tranexamic acid **OR** 3. The patient has an FDA labeled contraindication to BOTH aminocaproic acid AND tranexamic acid **OR** 4. There is support for the use of the requested agent over BOTH aminocaproic acid AND tranexamic acid **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 BOTH aminocaproic acid AND tranexamic acid 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 requested agent will be used as perioperative management of bleeding AND BOTH of the following: A. The patient has mild (Factor X level 6-10%) or moderate (Factor X level 1-5%) hereditary Factor X deficiency **AND** B. ONE of the following: 1. The patient's medication history includes aminocaproic acid or tranexamic acid used for the requested indication AND ONE of the following: A. The patient has had an inadequate response to aminocaproic acid or tranexamic acid used for the requested indication **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent aminocaproic acid or tranexamic acid used for the requested indication **OR** 2. The patient has an intolerance or hypersensitivity to aminocaproic acid or tranexamic acid **OR** 3. The patient has an FDA labeled contraindication to BOTH aminocaproic acid AND tranexamic acid **OR** 4. There is support for the use of the requested agent over BOTH aminocaproic

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	acid AND tranexamic acid **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 BOTH aminocaproic acid AND tranexamic acid 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 prescriber is a specialist (e.g., hematologist) in the area of the patient's diagnosis or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 3. The patient does NOT have liver disease **AND** 4. The patient does NOT have vitamin K deficiency **AND** 5. The patient will NOT be using the requested agent in combination with an indirect or direct Factor Xa inhibitor (e.g., apixaban [Eliquis[, dalteparin [Fragmin], edoxaban [Savaysa], enoxaparin [Lovenox], fondaparinux [Arixtra], rivaroxaban [Xarelto] or warfarin [Coumadin]) **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** One time emergency use: 1 time Perioperative management of bleeding: 1 time per request On-demand treatment: 3 months Prophylaxis treatment: 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit criteria.
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 > 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 ≥ 200 BU (lab records required) **OR** C. The patient is not a candidate for ITI **AND**

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	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 ≥ 20% decrease in inhibitor level over the last 6 months and needs further treatment to eradicate inhibitors) (medical record 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 > 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 ≥ 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 ≥ 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 > 5 on-demand doses on hand **OR** B. There is support for the patient having more than 5 on-demand

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	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 > 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 > 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, 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** 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:** CMS Approved Compendia **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 refer to Quantity Limit criteria.
Sevenfact	**Sevenfact** will be approved when ALL of the following are met: 1. ONE of the following:

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	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, 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., 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 > 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 refer to Quantity Limit criteria.
Target Agents EXCEPT Coagadex, NovoSeven RT, and Sevenfact	**Initial Evaluation** **Target Agent(s) EXCEPT Coagadex, NovoSeven RT, and Sevenfact** will be approved when ALL of the following are met: 1. ONE of the following: A. The patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR** B. 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** C. 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** D. BOTH of the following: 1. If patient has an FDA labeled diagnosis for the requested agent including intended use (i.e., prophylaxis, ITT/ITI, on-demand, peri-operative), then ONE of the following: A. If the patient has a diagnosis of hemophilia A (also known as Factor VIII deficiency or classic hemophilia), then BOTH of the following: 1. If the requested agent is being used for prophylaxis OR Immune Tolerance Therapy (ITT)/Immune Tolerance Induction (ITI), then the patient will NOT be using the requested agent in combination with Hemlibra (emicizumab-kxwh) **AND** 2. If the patient has mild hemophilia A (i.e., factor VIII activity level between 5%-40%) ONE of the following: A. The patient's medication history includes desmopressin (e.g., DDAVP injection, Stimate nasal spray) used for the requested indication AND ONE of the following: 1. The patient has had an inadequate response to desmopressin used for the requested indication **OR** 2. The prescriber has submitted an evidence-based and peer-

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	reviewed clinical practice guideline supporting the use of the requested agent desmopressin **OR** B. 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** C. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to therapy with desmopressin **OR** D. The prescriber has provided information supporting why the patient cannot use desmopressin (e.g., shortage in marketplace) **OR** E. The prescriber has provided documentation that desmopressin 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. If the patient has a diagnosis of Type 1, Type 2A, Type 2M, or Type 2N von Willebrand Disease (VWD), then ONE of the following: 1. The patient's medication history includes desmopressin (e.g., DDAVP injection, Stimate nasal spray) used for the requested indication AND ONE of the following: A. The patient has had an inadequate response to desmopressin used for the requested indication **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent desmopressin **OR** 2. 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** 3. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to therapy with desmopressin **OR** 4. The patient cannot use desmopressin (e.g., shortage in marketplace) **OR** 5. The prescriber has provided documentation that desmopressin acetate 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, 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 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**

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	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: 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 <1% factor activity, moderate is ≥1 to ≤5% factor activity, mild is >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 class included in this program **OR** B. There is support for the use of more than one unique agent in the same class (medical record 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 ITT/ITI: up to 6 months NOTE: If Quantity Limit applies, please refer to Quantity Limit criteria. **Renewal Evaluation** **Target Agent(s) EXCEPT Coagadex, NovoSeven RT, and Sevenfact** 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 the patient ONLY has previous approval(s) for emergency use, must use Initial Evaluation) **AND** 2. If the patient is using the requested agent for Hemophilia A prophylaxis OR ITT/ITT, the patient will NOT be using the requested agent in combination with Hemlibra (emicizumab-kxwh) **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/ITT, 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 <1% factor activity, moderate is ≥1 to ≤5% factor activity, mild is >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 >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 class included in this program **OR** B. There is support for the use of more than one unique agent in the same class (medical record required) **AND** 8. If the patient is using Immune Tolerance Therapy (ITT)/Immune Tolerance Induction (ITI), then BOTH of the

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	following: A. The patient will NOT be using the requested agent in combination with Hemlibra (emicizumab-kxwh) **AND** B. ONE of the following: (medical record 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 ≥ 20% decrease in inhibitor level over the last 6 months and needs further treatment to eradicate inhibitors) **Length of Approval:** On-demand: up to 3 months Peri-operative dosing: 1 time per request 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 refer to Quantity Limit criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Coagadex	**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 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., on-demand, perioperative management of bleeding, prophylaxis) **OR** 2. There is support for exceeding the defined program quantity limit (dose and/or number of doses) (medical records) **Length of Approval:** One time emergency use: 1 time Perioperative management of bleeding: 1 time per request On-demand treatment: up to 3 months Prophylaxis treatment: up to 12 months
NovoSeven RT	**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 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 All other diagnoses: up to 3 months

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Sevenfact	**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 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
Target Agents EXCEPT Coagadex, NovoSeven RT, and Sevenfact	**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 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/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 Initial ITT/ITI: up to 6 months 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: Insulin Pumps

Applies to:	☑ Medicaid Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ 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
	97201030506400	Omnipod 5 g6 intro kit (g ; Omnipod 5 g7 intro kit (g	*insulin infusion disposable pump kit***		M ; N ; O ; Y	08508300001 ; 08508300050			
	97201030506300	Omnipod 5 g6 pods (gen 5) ; Omnipod 5 g7 pods (gen 5) ; Omnipod classic pods (gen ; Omnipod dash pods (gen 4)	*Insulin Infusion Disposable Pump Supplies***		M ; N ; O ; Y				
	97201030506400	Omnipod classic pdm start	*insulin infusion disposable pump kit***		M ; N ; O ; Y	08508114002			
	97201030506400	Omnipod dash intro kit (g	*insulin infusion disposable pump		M ; N ; O ; Y	08508200032			

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
			kit***						
	97201030506400	Omnipod dash pdm kit (gen	*insulin infusion disposable pump kit***		M ; N ; O ; Y	08508200000			
	97201030506410	Omnipod go 10 units/day	*insulin infusion disposable pump kit	10 UNIT/24HR	M ; N ; O ; Y				
	97201030506415	Omnipod go 15 units/day	*insulin infusion disposable pump kit	15 UNIT/24HR	M ; N ; O ; Y				
	97201030506420	Omnipod go 20 units/day	*insulin infusion disposable pump kit	20 UNIT/24HR	M ; N ; O ; Y	08508400020			
	97201030506425	Omnipod go 25 units/day	*insulin infusion disposable pump kit	25 UNIT/24HR	M ; N ; O ; Y				
	97201030506430	Omnipod go 30 units/day	*insulin infusion disposable pump kit	30 UNIT/24HR	M ; N ; O ; Y	08508400030			
	97201030506435	Omnipod go 35 units/day	*insulin infusion disposable pump kit	35 UNIT/24HR	M ; N ; O ; Y				
	97201030506440	Omnipod go 40 units/day	*insulin infusion disposable pump kit	40 UNIT/24HR	M ; N ; O ; Y	08508400040			

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. ONE of the following: A. The patient has been using the requested product within the past 90 days **OR** B. The prescriber states the patient has been using the requested product within the past 90 days AND is at risk if therapy is changed **OR** C. ALL of the following: 1. The patient has diabetes mellitus AND requires insulin therapy **AND** 2. The patient is on an insulin regimen of 3 or more injections per day **AND** 3. The patient performs 4 or more blood glucose tests per day or is using Continuous Glucose Monitoring (CGM) **AND** 4. The patient has completed a comprehensive diabetes education program **AND** 5. The patient has demonstrated willingness and ability to play an active role in diabetes self-management **AND** 6. The patient has had ONE of the following while compliant on an optimized multiple daily insulin injection regimen: A. Glycosylated hemoglobin level (HbA1C) greater than 7% **OR** B. History of recurring hypoglycemia **OR** C. Wide fluctuations in blood glucose before mealtime **OR** D. Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL **OR** E. History of severe glycemic excursions **AND** 2. ONE of the following: A. The patient's age is within the manufacturer recommendations for the requested indication for the requested product **OR** B. There is support for using the requested product for the patient's age **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

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

Applies to:	☑ Medicaid Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ 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
	<table><tr><th>Indication</th><th>PDL Preferred Agents</th></tr><tr><td>Atopic Dermatitis</td><td>Dupixent</td></tr></table> **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: <table><tr><th>Agents Eligible for Continuation of Therapy</th></tr><tr><td>All target agents are eligible for continuation of therapy</td></tr></table>

Module	Clinical Criteria for Approval
	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 submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL medium-, high-, and super-potency topical corticosteroids used in the treatment of AD **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

Module	Clinical Criteria for Approval
	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 submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL topical calcineurin inhibitors used in the treatment of AD **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. ONE of the following: A. The requested agent is a preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) **OR** B. The request is for a non-preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) and ONE of the following: 1. The patient is currently being treated with the requested agent and is experiencing a positive therapeutic outcome AND the prescriber provides documentation that switching the member to a preferred drug is expected to cause harm to the member or that the preferred drug would be ineffective **OR** 2. The patient has tried and had an inadequate response to two preferred chemically unique agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) as indicated by BOTH of the following: A. ONE of the following: 1. Evidence of a paid claim(s) **OR** 2. The prescriber has stated that the patient has tried the required prerequisite/preferred agent(s) **AND** B. ONE of the following: 1. The required prerequisite/preferred agent(s) was discontinued due to lack of effectiveness or an adverse event **OR**

Module	Clinical Criteria for Approval
	2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over the prerequisite/preferred agent(s) **OR** C. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to the preferred agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) that is not expected to occur with the requested agent **OR** D. The prescriber has provided documentation that the required prerequisite/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** E. The prescriber has submitted documentation supporting the use of the non-preferred agent over the preferred agent(s) **AND** 5. 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** 6. 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** 7. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** CMS Approved Compendia **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

Module	Clinical Criteria for Approval
	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**: CMS Approved Compendia **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

Module	Clinical Criteria for Approval
	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) 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)

Contraindicated as Concomitant Therapy
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: Ocaliva (obeticholic acid)

Applies to:	☑ Medicaid Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ 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**

Module	Clinical Criteria for Approval
	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**

Module	Clinical Criteria for Approval
	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: Otezla (apremilast)

Applies to:	☑ Medicaid Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ 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**

Module	Clinical Criteria for Approval

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 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**
            2. The patient's medication history includes ONE conventional agent (i.e., cyclosporine, leflunomide, methotrexate, sulfasalazine) used in the treatment of PsA AND ONE of the following:
               A. The patient has had an inadequate response to a conventional agent (i.e., cyclosporine, leflunomide, methotrexate, sulfasalazine) used in the treatment of PsA **OR**
               B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over a conventional agent (i.e., cyclosporine, leflunomide, methotrexate, sulfasalazine) used in the treatment of PsA **OR**
            3. The patient has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of PsA **OR**
            4. The patient has an FDA labeled contraindication to ALL of the conventional agents used in the treatment of PsA **OR**
            5. 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**
            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**

Module	Clinical Criteria for Approval
	2. The patient weighs at least 20 kg **AND** 2. 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 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 AND ONE of the following: 1. The patient has had an inadequate response to a 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 **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over 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 **OR** C. The patient has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of PS **OR** D. The patient has an FDA labeled contraindication to ALL conventional agents used in the treatment of PS **OR** E. 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** 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 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

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	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 ONE conventional agent (i.e., topical oral corticosteroids [i.e., triamcinolone dental paste], colchicine, azathioprine) used in the treatment of BD AND ONE OF the following: 1. The patient has had an inadequate response to a conventional agent (i.e., topical oral corticosteroids [i.e., triamcinolone dental paste], colchicine, azathioprine) used in the treatment of BD **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over conventional agent (i.e., topical oral corticosteroids [i.e., triamcinolone dental paste], colchicine, azathioprine) used in the treatment of BD **OR** C. The patient has an intolerance or hypersensitivity to ONE conventional agent used in the treatment of BD **OR** D. The patient has an FDA labeled contraindication to ALL conventional agents used in the treatment of BD **OR** E. 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** 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. ONE of the following: A. The requested agent is a preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) **OR** B. The request is for a non-preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) and ONE of the following: 1. 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

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	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** 2. The patient has tried and had an inadequate response to two preferred chemically unique agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) as indicated by BOTH of the following: A. ONE of the following: 1. Evidence of a paid claim(s) **OR** 2. The prescriber has stated that the patient has tried the required prerequisite/preferred agent(s) **AND** B. ONE of the following: 1. The required prerequisite/preferred agent(s) was discontinued due to lack of effectiveness or an adverse event **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over the prerequisite/preferred agent(s) **OR** 3. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to the preferred agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) that is not expected to occur with the requested agent **OR** 4. The prescriber has provided documentation that the required prerequisite/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** 5. The prescriber has submitted documentation supporting the use of the non-preferred agent over the preferred agent(s) **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 **Compendia Allowed:** CMS approved compendia **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**

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	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)

Contraindicated as Concomitant Therapy
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: Sunosi (solriamfetol)

Applies to:	☑ Medicaid Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ 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's medication history armodafinil OR modafinil AND ONE of the following: 1. The patient has had an inadequate response to armodafinil OR modafinil **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over BOTH armodafinil AND 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's medication history armodafinil OR modafinil AND ONE of the following: A. The patient has had an inadequate response to armodafinil OR modafinil **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over BOTH armodafinil AND

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	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 the 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:	☑ Medicaid Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ 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				

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
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
PA	**Initial Evaluation** **Target Agent(s)** will be approved when ONE of the following are met: 1. ALL of the following: A. ONE of the following: 1. The requested agent is Doptelet AND ONE of the following: A. The patient has a diagnosis of chronic (defined as lasting for at least 12 months) immune (idiopathic) thrombocytopenia (ITP) AND BOTH of the following: 1. ONE of the following: A. The patient has a platelet count less than or equal to 30 X 10^9/L **OR** B. 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** 2. ONE of the following: A. The patient's medication history includes ONE corticosteroid used for the treatment of ITP AND ONE of the following: 1. The patient has had an inadequate response to ONE corticosteroid used for the treatment of ITP **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over corticosteroid used for the treatment of ITP **OR** B. The patient has an intolerance or hypersensitivity to ONE corticosteroid used for the treatment of ITP **OR** C. The patient has an FDA labeled contraindication to ALL corticosteroids used for the treatment of ITP **OR** D. The patient has tried and had an inadequate response to another thrombopoietin receptor agonist (e.g., Nplate, Promacta) or Tavalisse **OR** E. The patient has tried and had an inadequate response to immunoglobulins (IVIg or Anti-D) **OR** F. The patient has had an inadequate response to a splenectomy **OR** G. The patient has tried and had an inadequate response to rituximab **OR** H. 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

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	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** I. 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** B. The patient has a diagnosis of thrombocytopenia and has chronic liver disease AND ALL of the following: 1. The patient has a platelet count less than 50 X 10^9/L **AND** 2. The patient is scheduled to undergo a procedure with an associated risk of bleeding (e.g., gastrointestinal endoscopy, liver biopsy, bronchoscopy, dental procedure) **AND** 3. The patient would require a platelet transfusion unless platelet counts are clinically increased from baseline (prior to therapy with the requested agent) **OR** C. The patient has another FDA labeled indication for the requested agent **OR** D. The patient has another indication that is supported in compendia for the requested agent and route of administration **OR** 2. The requested agent is Mulpleta (lusutrombopag) AND ONE of the following: A. The patient has a diagnosis of thrombocytopenia and has chronic liver disease AND ALL of the following: 1. The patient has a platelet count less than 50 X 10^9/L **AND** 2. The patient is scheduled to undergo a procedure with an associated risk of bleeding (e.g., gastrointestinal endoscopy, liver biopsy, bronchoscopy, dental procedure) **AND** 3. The patient would require a platelet transfusion unless platelet counts are clinically increased from baseline (prior to therapy with the requested agent) **OR** B. The patient has another FDA labeled indication for the requested agent **OR** C. The patient has another indication that is supported in compendia for the requested agent and route of administration **OR** 3. The requested agent is Nplate (romiplostim) AND ONE of the following: A. The patient has a diagnosis of hematopoietic syndrome of acute radiation syndrome (HS-ARS) **OR** B. The patient has a diagnosis of immune (idiopathic) thrombocytopenia (ITP) AND ALL of the following: 1. If the patient is a pediatric patient, then the patient has had ITP for at least 6 months **AND** 2. ONE of the following: A. The patient has a platelet count less than or equal to 30 X 10^9/L **OR** B. 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** 3. ONE of the following: A. The patient's medication history includes ONE corticosteroid used for the treatment of ITP AND ONE of the following: 1. The patient has had an inadequate response to ONE corticosteroid used for the treatment of ITP **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over corticosteroid used for the treatment of

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	ITP **OR** B. The patient has an intolerance or hypersensitivity to ONE corticosteroid used for the treatment of ITP **OR** C. The patient has an FDA labeled contraindication to ALL corticosteroids used for the treatment of ITP **OR** D. The patient has tried and had an inadequate response to immunoglobulins (IVIg or anti-D) **OR** E. The patient has had an inadequate response to a splenectomy **OR** F. The patient has tried and had an inadequate response to rituximab **OR** G. 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** H. 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** C. The patient has another FDA labeled indication for the requested agent **OR** D. The patient has another indication that is supported in compendia for the requested agent and route of administration **OR** 4. The requested agent is Promacta (eltrombopag) or Alvaiz AND ONE of the following: A. The patient has a diagnosis of hepatitis C associated thrombocytopenia AND ONE of the following: 1. 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** 2. The patient is on concomitant therapy with interferon AND is at risk for discontinuing hepatitis C therapy due to thrombocytopenia **OR** B. The patient has a diagnosis of severe aplastic anemia AND ALL of the following: 1. The patient has at least 2 of the following blood criteria: A. Neutrophils less than 0.5 X 10^9/L B. Platelets less than 30 X 10^9/L C. Reticulocyte count less than 60 X 10^9/L **AND** 2. The patient has 1 of the following marrow criteria: A. Severe hypocellularity: less than 25% **OR** B. Moderate hypocellularity, 25-50% with hematopoietic cells representing less than 30% of residual cells **AND** 3. ONE of the following: A. BOTH of the following: 1. The patient will use the requested agent as first-line treatment **AND** 2. The patient will use the requested agent in combination with standard immunosuppressive therapy (i.e., antithymocyte globulin [ATG] AND cyclosporine) **OR** B. ONE of the following: 1. The patient's medication history includes BOTH antithymocyte globulin (ATG) AND cyclosporine therapy AND ONE of the following:

Module	Clinical Criteria for Approval
	A. The patient has had an inadequate response to BOTH antithymocyte globulin (ATG) AND cyclosporine therapy **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over 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** 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 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** C. 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: 1. ONE of the following: A. The patient has a platelet count less than or equal to 30 x 10^9/L **OR** B. 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** 2. ONE of the following: A. The patient's medication history includes ONE corticosteroid used for the treatment of ITP AND ONE of the following: 1. The patient has had an inadequate response to ONE corticosteroid used for the treatment of ITP **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over corticosteroid used for the treatment of ITP **OR** B. The patient has an intolerance or hypersensitivity to ONE corticosteroid used for the treatment of ITP **OR** C. The patient has an FDA labeled contraindication to ALL corticosteroids used for the treatment of ITP **OR** D. The patient has tried and had an inadequate response to immunoglobulins (IVIg or anti-D) **OR** E. The patient has had an inadequate response to a splenectomy **OR** F. The patient has tried and had an inadequate response to rituximab **OR** G. The patient is currently being treated with the requested agent as indicated by ALL of the following:

Module	Clinical Criteria for Approval
	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** H. 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** D. The patient has another FDA labeled indication for the requested agent **OR** E. The patient has another indication that is supported in compendia for the requested agent and route of administration **OR** 5. The requested agent is Alvaiz (eltrombopag) AND ONE of the following: A. The patient has a diagnosis of hepatitis C associated thrombocytopenia AND ONE of the following: 1. 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** 2. The patient is on concomitant therapy with interferon AND is at risk for discontinuing hepatitis C therapy due to thrombocytopenia **OR** B. The patient has a diagnosis of severe aplastic anemia AND ALL of the following: 1. The patient has at least 2 of the following blood criteria: A. Neutrophils less than 0.5 X 10^9/L B. Platelets less than 30 X 10^9/L C. Reticulocyte count less than 60 X 10^9/L **AND** 2. The patient has 1 of the following marrow criteria: A. Severe hypocellularity: less than 25% **OR** B. Moderate hypocellularity, 25-50% with hematopoietic cells representing less than 30% of residual cells **AND** 3. 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** C. 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: 1. ONE of the following: A. The patient has a platelet count less than or equal to 30 x 10^9/L **OR** B. 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** 2. ONE of the following: A. The patient has tried and had an inadequate response to ONE corticosteroid used for the treatment of ITP **OR** B. The patient has an intolerance or hypersensitivity to ONE corticosteroid used for the treatment of ITP **OR** C. The patient has an FDA labeled contraindication to ALL corticosteroids used for the treatment of ITP **OR** D. The patient has tried and had an inadequate response to

Module	Clinical Criteria for Approval
	immunoglobulins (IVIg or anti-D) **OR** E. The patient has had an inadequate response to a splenectomy **OR** F. The patient has tried and had an inadequate response to rituximab **OR** G. 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** H. 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** D. The patient has another FDA labeled indication for the requested agent **OR** E. The patient has another indication that is supported in compendia for the requested agent and route of administration **OR** 6. The requested agent is Tavalisse (fostamatinib disodium hexahydrate) AND ONE of the following: A. The patient has a diagnosis of chronic (defined as lasting for at least 12 months) immune (idiopathic) thrombocytopenia (ITP) AND BOTH of the following: 1. ONE of the following: A. The patient has a platelet count less than or equal to 30 X 10^9/L **OR** B. 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** 2. ONE of the following: A. The patient's medication history includes ONE corticosteroid used for the treatment of ITP AND ONE of the following: 1. The patient has had an inadequate response to ONE corticosteroid used for the treatment of ITP **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over corticosteroid used for the treatment of ITP **OR** B. The patient has an intolerance or hypersensitivity to ONE corticosteroid used for the treatment of ITP **OR** C. The patient has an FDA labeled contraindication to ALL corticosteroids used for the treatment of ITP **OR** D. The patient has tried and had an inadequate response to another thrombopoietin receptor agonist (e.g., Doptelet, Nplate, Promacta) **OR** E. The patient has tried and had an inadequate response to immunoglobulins (IVIg or Anti-D) **OR** F. The patient has had an inadequate response to a splenectomy **OR** G. The patient has tried and had an inadequate response to rituximab **OR** H. 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**

Module	Clinical Criteria for Approval
	3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** I. 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** B. The patient has another FDA labeled indication for the requested agent **OR** C. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND** B. If the patient has an FDA labeled indication, then ONE of the following: 1. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** 2. There is support for using the requested agent for the patient's age for the requested indication **AND** C. ONE of the following: 1. The patient will NOT be using the requested agent in combination with another agent included in this program **OR** 2. The patient will use the requested agent in combination with another agent included in this program AND BOTH of the following: A. The requested agent is Nplate **AND** B. The patient has a diagnosis of hematopoietic syndrome of acute radiation syndrome (HS-ARS) **AND** D. The patient does NOT have any FDA labeled contraindications to the requested agent **OR** 2. If the request is for an oral liquid form of a medication, then BOTH of the following: A. The patient has an FDA labeled indication **AND** B. The patient uses an enteral tube for feeding or medication administration **Compendia Allowed:** CMS Approved Compendia **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 BOTH 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**

Module	Clinical Criteria for Approval
	2. ONE of the following: A. ALL of the following: 1. 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 had clinical benefit with the requested agent **AND** 2. The patient will NOT be using the requested agent in combination with another agent included in this program **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **OR** B. If the request is for an oral liquid form of a medication, then BOTH of the following: 1. The patient has an FDA labeled indication **AND** 2. The patient uses an enteral tube for feeding or medication administration **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

Module	Clinical Criteria for Approval
	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:	☑ Medicaid Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ 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				
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	**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**

Module	Clinical Criteria for Approval
	3. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** CMS approved compendia **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 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:	☑ Medicaid Formularies
Type:	☑ Prior Authorization ☑ Quantity Limit ☐ Step Therapy ☐ 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

Module	Clinical Criteria for Approval
	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