COMMERCIAL PHARMACY PROGRAM POLICY ACTIVITY

Provider Notification

Policies Effective: December 1, 2023 Notification Posted: October 17, 2023

BlueCross BlueShield Minnesota

Contents

NEW POLICIES DEVELOPED

No new policies for December 1, 2023

POLICIES REVISED

• Program Summary: Androgens and Anabolic Steroids

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

TARGET AGENT(S)

Topical Androgen Agents:

Androderm® (testosterone transdermal system)

AndroGel®

Fortesta® (testosterone gel)[a]

Natesto® (testosterone nasal gel)

Testim® (testosterone gel)[a]

Testosterone solution

Vogelxo® (testosterone gel)[a]

a – Generic available and included in prior authorization and quantity limit programs.

PROGRAM QUANTITY LIMITS – TOPICAL ANDROGENS

Brand (generic)	GPI	Multisource Code	Quantity Limit (per day or as listed)
Topical Androgen Agents			
Androderm (testosterone transdermal system)			
2 mg/day transdermal system	23100030008503	M, N, O, or Y	1 patch
4 mg/day transdermal system	23100030008510	M, N, O, or Y	1 patch
AndroGel (testosterone gel)			
1% gel, 2.5 g packet[a]	23100030004025	M, N, O, or Y	2 packets (5 g)
1% gel, 5 g packet[a]	23100030004030	M, N, O, or Y	2 packets (10 g)
1% gel, 75 g pump bottle (1.25 g/actuation; 60 actuations/pump bottle)[a]	23100030004040	M, N, O, or Y	8 actuations/day, 4 pump bottles/30 days (10 g/day)
1% gel, 2 x 75 g pump bottle (1.25 g/actuation; 60 actuations/pump bottle)[a]	23100030004040	M, N, O, or Y	8 actuations/day, 4 pump bottles/30 days (10 g/day)
1.62% gel, 1.25 g packet[a]	23100030004044	M, N, O, or Y	1 packet (1.25 g/day)
1.62% gel, 2.5 g packet[a]	23100030004047	M, N, O, or Y	2 packets (5 g/day)
1.62% gel, 75 g pump-bottle (1.25 g/actuation; 60 actuations/pump bottle)[a]	23100030004050	M, N, O, or Y	4 actuations/day, 2 pump-bottles/30 days (5 g/day)
testosterone solution			
30 mg/1.5 mL, 90 mL pump bottle (1.5 mL/actuation; 60 actuations/pump bottle)[a]	23100030002020	M, N, O, or Y	4 actuations/day, 2 pump bottles/30 days (6 mL/day)
Fortesta (testosterone gel)			
2% gel, 60 g pump bottle (0.5 g/actuation; 120 actuation/pump bottle) [a,b]	23100030004070	M, N, O, or Y	8 actuations/day, 2 pump bottles/30 days (4 g/day)
Natesto (testosterone nasal gel)			
5.5 mg/0.122g, 11 g pump bottle (0.122 g/actuation; 60 actuations/pump bottle)	23100030004080	M, N, O, or Y	6 actuations/day, 3 pump bottles/30 days (0.732 g/day)
Testim / Testosterone (testosterone gel)			
1% gel, 5 g tube[a]	23100030004030	M, N, O, or Y	2 tubes (10 g)
Vogelxo / Testosterone (testosterone gel)			
1% gel, 50 mg/5 g tube	23100030004030	M, N, O, or Y	2 tubes (10 g)
1% gel, 50 mg/5 g packet	23100030004030	M, N, O, or Y	2 packets (10 g)
1% gel, 75 g pump bottle (12.5 mg/actuation; 60 actuations/ pump bottle)	23100030004040	M, N, O, or Y	8 actuations/day, 4 pump bottles/30 days (10 g/day)

a – Generic available and included in prior authorization and quantity limit programs

b – Quantity limit adjusted to accommodate packaging of agent

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Initial Evaluation

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

1. ONE of the following:
    A. If the request is for Androderm, Androgel, Testosterone gel, testosterone solution, Fortesta, Natesto, Testim, or Vogelxo, the patient has a diagnosis of ONE of the following:
        i. Primary or secondary (hypogonadotropic) hypogonadism

OR

ii. AIDS/HIV-associated wasting syndrome

OR

iii. Gender identity disorder (GID), gender dysphoria, or gender incongruence

OR

B. If the request is for Depo-Testosterone, testosterone enanthate, or Xyosted, the patient has a diagnosis of ONE of the following:
   i. Primary or secondary (hypogonadotropic) hypogonadism
   OR
   ii. AIDS/HIV-associated wasting syndrome
   OR
   iii. Delayed puberty in an adolescent
   OR
   iv. Metastatic/inoperable breast cancer
   OR
   v. Gender identity disorder (GID), gender dysphoria, or gender incongruence

OR

C. If the request is for Testopel, the patient has a diagnosis of ONE of the following:
   i. Primary or secondary (hypogonadotropic) hypogonadism
   OR
   ii. Delayed puberty in an adolescent
   OR
   iii. Gender identity disorder (GID), gender dysphoria, or gender incongruence

OR

D. If the request is for danazol, the patient has a diagnosis of ONE of the following:
   i. Endometriosis amenable to hormone management
   OR
   ii. Angioedema and will be taking for the prevention of attacks
   OR
   iii. Myeloproliferative neoplasms
   OR
   iv. Fibrocystic breast disease

OR

E. If the request is for oxandrolone, the requested agent will be used for ONE of the following:
   i. To promote weight gain
   OR
   ii. Bone pain frequently accompanying osteoporosis
   OR
   iii. AIDS/HIV-associated wasting syndrome
   OR
   iv. Turner syndrome
   OR
   v. Gender identity disorder (GID), gender dysphoria, or gender incongruence

OR

F. If the request is for Jatenzo, the patient has a diagnosis of primary or secondary (hypogonadotropic) hypogonadism

OR

G. If the request is for Aveed, the patient has a diagnosis of ONE of the following:
   i. Primary or secondary (hypogonadotropic) hypogonadism
   OR
   ii. Gender identity disorder (GID), gender dysphoria, or gender incongruence

OR

H. If the request is for methyltestosterone or Methitest, the patient has a diagnosis of ONE of the following:
   i. Primary or secondary (hypogonadotropic) hypogonadism

OR

ii. Metastatic/inoperable breast cancer

OR

iii. Delayed puberty in an adolescent

AND

2. ONE of the following:
   A. If the request is for primary or secondary hypogonadism, then ONE of the following:
      i. The patient is NOT currently receiving testosterone replacement therapy AND meets BOTH of the following:
         a. The patient has a sign or symptom of hypogonadism

         AND

         b. The patient has ONE of the following pretreatment levels:
            1. Total serum testosterone level that is below the testing laboratory's normal range or is less than 300 ng/dL

            OR

            2. Free serum testosterone level that is below the testing laboratory's normal range

      OR

      ii. The patient is currently receiving testosterone replacement therapy AND has ONE of the following current levels:
         a. Total serum testosterone level that is within OR below the testing laboratory's normal range OR is less than 300 ng/dL

         OR

         b. Free serum testosterone level that is within OR below the testing laboratory's normal range

   OR

   B. If the request is for AIDS/HIV-associated wasting syndrome, BOTH of the following:
      i. ONE of the following:
         a. The patient has had an unintentional weight loss that meets ONE of the following:
            1. 10% within 12 months

            OR

            2. 7.5% within 6 months

         OR

         b. The patient has a body cell mass (BCM) loss greater than or equal to 5% within 6 months

         OR

         c. The patient's sex is male and has BCM less than 35% of total body weight and body mass index (BMI) less than 27 kg/ m^2

         OR

         d. The patient's sex is female and has BCM less than 23% of total body weight and BMI less than 27 kg/ m^2

         OR

         e. The prescriber has provided information that the patient's BCM less than 35% or less than 23% and BMI less than 27 kg/ m^2 are medically appropriate for diagnosing AIDS wasting/cachexia for the patient's sex

         OR

         f. The patient's BMI is less than 20 kg/m^2

      AND

      ii. All other causes of weight loss have been ruled out

   OR

   C. If the request is for gender identity disorder (GID), gender dysphoria, or gender incongruence, ONE of the following:
      i. The patient is an adolescent and ONE of the following:
         a. The patient is initiating sex hormone treatment AND ALL of the following:
            1. A persistent diagnosis was confirmed by a mental health professional and/or trained physician who is trained in child and adolescent developmental psychopathology

            AND

2. The patient's indication for sex hormone treatment has been confirmed by an endocrinologist OR clinician experienced in pubertal sex hormone induction
AND
3. The patient does not have any medical contraindications to sex hormone treatment as confirmed by an endocrinologist OR clinician experienced in pubertal sex hormone induction
AND
4. The patient has been informed and counseled regarding effects and side effects of sex hormone treatment including those which are irreversible, and regarding loss of fertility and options to preserve fertility
AND
5. ONE of the following:
    A. The patient is 16 years of age or over
    OR
    B. The prescriber has provided information in support of initiating therapy prior to 16 years of age
AND
6. The patient has sufficient mental capacity to give consent
AND
7. The patient has provided consent AND, as applicable, the parents or other caretakers or guardians have provided consent to therapy
AND
8. The patient's coexisting psychological, medical, or social problems that could interfere with treatment have been addressed and the patient's functioning is stable enough to start sex hormone therapy

OR

b. The patient is continuing therapy with sex hormone treatment AND the patient is being monitored at least once per year

OR

ii. The patient is an adult AND ONE of the following:
a. The patient is initiating sex hormone treatment AND ALL of the following:
1. A persistent diagnosis has been confirmed by a mental health professional
AND
2. The patient has sufficient mental capacity to give consent
AND
3. The patient's coexisting mental health concerns, if present, are reasonably well controlled
AND
4. The patient's medical conditions that can be exacerbated by treatment with sex hormones have been evaluated and addressed

OR

b. The patient is currently on sex hormone treatment and BOTH of the following:
1. ONE of the following:
    A. The patient's current testosterone level is ONE of the following:
        i. Total serum testosterone level that is within OR below the testing laboratory's normal range OR is less than 300 ng/dL
        OR
        ii. Free serum testosterone level that is within OR below the testing laboratory's normal range
    OR
    B. The prescriber has provided information in support of continuing therapy with the patient's current testosterone level
AND
2. The patient is being monitored at least once per year

OR

D. If the request is for delayed puberty in an adolescent, then ONE of the following:
   i. The patient's sex is male
      OR
   ii. The prescriber has provided information that the requested agent is medically appropriate for the patient's sex

OR

E. If the request is for metastatic/inoperable breast cancer, then ONE of the following:
   i. The patient's sex is female
      OR
   ii. The prescriber has provided information that the requested agent is medically appropriate for the patient's sex

OR

F. If the request is for anemia, the anemia is associated with ONE of the following:
   i. Deficient red cell production
      OR
   ii. Acquired aplastic anemia
      OR
   iii. Congenital aplastic anemia
      OR
   iv. Myelofibrosis
      OR
   v. Hypoplastic anemia due to the administration of myelotoxic drugs

OR

G. The request is for fibrocystic breast disease

OR

H. The request is for endometriosis amenable to hormone management

OR

I. The request is for the prevention of attacks of angioedema

OR

J. If the request is for myeloproliferative neoplasms, ONE of the following:
   i. Patient has a serum EPO greater than or equal to 500 mU/mL
      OR
   ii. Patient has a serum EPO less than 500 mU/mL and no response or loss of response to erythropoietic stimulating agents

OR

K. If the request is for Turner syndrome, the agent will be used in conjunction with growth hormone (GH)

OR

L. The request is for bone pain frequently accompanying osteoporosis

OR

M. If the request is to promote weight gain, the patient has ONE of the following:
   i. weight loss following extensive surgery
      OR
   ii. chronic infections
      OR
   iii. severe trauma
      OR
   iv. failure to gain or maintain normal weight without definite pathophysiologic reasons
      OR
   v. a prolonged administration of corticosteroids

AND

3. The patient does NOT have any FDA labeled contraindications to the requested agent

AND

4. If the request is for one of the following brand agents, then ONE of the following:

Brand Agent(s)
Androderm
Androgel
Fortesta
Natesto
Testim
Testosterone
Vogelxo

A. The patient has tried and had an inadequate response to a generic androgen or anabolic steroid agent that is supported for use for the requested indication
OR
B. The patient has an intolerance or hypersensitivity to a generic androgen or anabolic steroid agent that is supported for use for the requested indication that is not expected to occur with the brand agent
OR
C. The patient has an FDA labeled contraindication to ALL generic androgen or anabolic steroid agents that is supported for use for the requested indication that is not expected to occur with the brand agent
OR
D. The patient is currently being treated with the requested agent as indicated by ALL of the following:
    i. A statement by the prescriber that the patient is currently taking the requested agent
    AND
    ii. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent
    AND
    iii. 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 generic androgen or anabolic steroid agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm

AND

5. ONE of the following:
    A. The patient will NOT be using the requested agent in combination with another androgen or anabolic steroid agent
    OR
    B. The prescriber has provided information in support of therapy with more than one androgen or anabolic steroid agent

AND

6. ONE of the following:
    A. The requested agent does NOT have a program quantity limit
    OR
    B. The requested quantity (dose) does NOT exceed the program quantity limit
    OR
    C. ALL of the following:
        i. The requested quantity (dose) exceeds the program quantity limit
        AND
        ii. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication
        AND
        iii. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit
    OR
    D. ALL of the following:
        i. The requested quantity (dose) exceeds the program quantity limit

AND

ii. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication
AND

iii. The prescriber has provided information in support of therapy with a higher dose for the requested indication

Length of Approval: 6 months (delayed puberty only)
12 months (all other indications)

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
AND
2. The patient has had clinical benefit with the requested agent
AND
3. ONE of the following:
    A. The patient has a diagnosis of primary or secondary hypogonadism and the patient's current testosterone level is ONE of the following:
        i. Total serum testosterone level that is within OR below the testing laboratory's normal range OR is less than 300 ng/dL
        OR
        ii. Free serum testosterone level that is within OR below the testing laboratory's normal range
    OR
    B. The patient has a diagnosis of gender identity disorder (GID), gender dysphoria, or gender incongruence AND ONE of the following:
        i. If the patient is an adult, BOTH of the following:
            a. The patient is being monitored at least once per year
            AND
            b. ONE of the following:
                1. The patient's current testosterone level is ONE of the following:
                    A. Total serum testosterone level that is within OR below the testing laboratory's normal range OR is less than 300 ng/dL
                    OR
                    B. Free serum testosterone level that is within OR below the testing laboratory's normal range
                OR
                2. The prescriber has provided information in support of continuing therapy with the patient's current testosterone level
        OR
        ii. If the patient is an adolescent, the patient is being monitored at least once per year
    OR
    C. The patient has a diagnosis other than primary or secondary hypogonadism, gender identity disorder (GID), gender dysphoria, or gender incongruence
AND
4. The patient does NOT have any FDA labeled contraindications to the requested agent
AND

5. If the request is for one of the following brand agents, then ONE of the following:

Brand Agent(s)
Androderm
Androgel
Fortesta
Natesto
Testim
Testosterone
Vogelxo

   A. The patient has tried and had an inadequate response to a generic androgen or anabolic steroid agent that is supported for use for the requested indication
   OR
   B. The patient has an intolerance or hypersensitivity to a generic androgen or anabolic steroid agent that is supported for use for the requested indication that is not expected to occur with the brand agent
   OR
   C. The patient has an FDA labeled contraindication to ALL generic androgen or anabolic steroid agents that is supported for use for the requested indication that is not expected to occur with the brand agent
   OR
   D. The patient is currently being treated with the requested agent as indicated by ALL of the following:
      i. A statement by the prescriber that the patient is currently taking the requested agent
      AND
      ii. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent
      AND
      iii. 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 generic androgen or anabolic steroid agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm

AND

6. ONE of the following:
   A. The patient will NOT be using the requested agent in combination with another androgen or anabolic steroid agent
   OR
   B. The prescriber has provided information in support of therapy with more than one androgen or anabolic steroid agent

AND

7. ONE of the following:
   A. The requested agent does NOT have a program quantity limit
   OR
   B. The requested quantity (dose) does NOT exceed the program quantity limit
   OR
   C. ALL of the following:
      i. The requested quantity (dose) exceeds the program quantity limit
      AND
      ii. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication
      AND
      iii. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit
   OR
   D. ALL of the following:

i. The requested quantity (dose) exceeds the program quantity limit
AND
ii. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication
AND
iii. The prescriber has provided information in support of therapy with a higher dose for the requested indication

Length of Approval: 12 months

• Program Summary: Antifungals

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
11507040100320	Brexafemme	Ibrexafungerp Citrate Tab	150 MG	4	Tablets	90	DAYS			
1140805000B220	Vivjoa	Oteseconazole Cap Therapy Pack	150 MG	18	Capsules	180	DAYS			

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Brexafemme	**Brexafemme (ibrexafungerp)** will be approved when BOTH of the following are met 1. ONE of the following: A. BOTH of the following: 1. The patient is an adult or post-menarchal pediatric patient AND ONE of the following: A. The requested agent will be used for the treatment of vulvovaginal candidiasis (VVC) **OR** B. BOTH of the following: 1. The patient is using the requested agent to reduce the incidence of recurrent vulvovaginal candidiasis (RVVC) **AND** 2. The patient has experienced greater than or equal to 3 episodes of vulvovaginal candidiasis (VVC) in a 12 months period **AND** 2. ONE of the following: A. The patient has tried and had an inadequate response to fluconazole for the current infection **OR** B. The patient has an intolerance or hypersensitivity to fluconazole **OR** C. The patient has an FDA labeled contraindication to fluconazole **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 fluconazole 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

Module	Clinical Criteria for Approval
	mental harm **OR** B. The patient has another FDA approved 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. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS, or DrugDex 1 or 2a level of evidence **Length of Approval:** 3 months for treatment of vulvovaginal candidiasis, 6 months for recurrent vulvovaginal candidiasis NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.
Cresemba	**Initial Evaluation** **Cresemba (isavuconazole)** will be approved when BOTH of the following are met: 1. ONE of the following: A. The patient has a diagnosis of invasive aspergillosis **OR** B. The patient has a diagnosis of invasive mucormycosis **OR** C. The patient has another FDA approved 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. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS, or DrugDex 1 or 2a level of evidence **Length of Approval:** 6 months **Renewal Evaluation** **Cresemba (isavuconazole)** 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 review process **AND** 2. ONE of the following: A. BOTH of the following: 1. The patient has a diagnosis of invasive aspergillosis **AND** 2. The patient has continued indicators of active disease (e.g., continued radiologic findings, positive cultures, positive serum galactomannan assay) **OR** B. BOTH of the following: 1. The patient has a diagnosis of invasive mucormycosis **AND** 2. The patient has continued indicators of active disease (e.g., continued radiologic findings, direct microscopy findings, histopathology findings, positive cultures, positive serum galactomannan assay) **OR** C. BOTH of the following: 1. The patient has another FDA approved indication or another indication that is supported in compendia for the requested agent and route of administration **AND** 2. The prescriber has submitted information supporting continued use of the requested agent for the requested indication **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent

Module	Clinical Criteria for Approval
	Compendia Allowed: AHFS, or DrugDex 1 or 2a level of evidence **Length of Approval:** 6 months
Noxafil	**Initial Evaluation** **Noxafil (posaconazole)** will be approved when ALL of the following are met: 1. ONE of the following: A. The patient has a diagnosis of oropharyngeal candidiasis AND ONE of the following: 1. The patient has tried and had an inadequate response to itraconazole or fluconazole **OR** 2. The patient has an intolerance or hypersensitivity to itraconazole or fluconazole **OR** 3. The patient has an FDA labeled contraindication to BOTH fluconazole AND itraconazole **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 fluconazole AND itraconazole 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. BOTH of the following: 1. The requested agent is prescribed for prophylaxis of invasive Aspergillus or Candida **AND** 2. The patient is severely immunocompromised (e.g., hematopoietic stem cell transplant (HSCT) recipients, a hematologic malignancy with prolonged neutropenia from chemotherapy), or is a high-risk solid organ (lung, heart-lung, heart, pancreas, liver, kidney, small bowel) transplant patient **OR** C. The patient has an infection caused by Scedosporium or Zygomycetes **OR** D. The patient has a diagnosis of invasive Aspergillus AND ONE of the following: 1. The patient has tried and had an inadequate response to voriconazole, amphotericin B, or isavuconazole **OR** 2. The patient has an intolerance or hypersensitivity to voriconazole, amphotericin B, or isavuconazole **OR** 3. The patient has an FDA labeled contraindication to voriconazole, amphotericin B, AND isavuconazole **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 voriconazole, amphotericin B, AND isavuconazole 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**

Module	Clinical Criteria for Approval
	E. The patient has another FDA approved indication for the requested agent and route of administration **OR** F. 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 approved indication, ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS, or DrugDex 1 or 2a level of evidence **Length of Approval:** 1 month for oropharyngeal candidiasis, 6 months for all other indications **Renewal Evaluation** **Noxafil (posaconazole)** 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 review process (NOTE: See initial criteria for a diagnosis of oropharyngeal candidiasis) **AND** 2. ONE of the following: A. BOTH of the following: 1. The requested agent is being prescribed for prophylaxis of invasive Aspergillus or Candida **AND** 2. The patient continues to be severely immunocompromised (e.g., hematopoietic stem cell transplant (HSCT) recipients, a hematologic malignancy with prolonged neutropenia from chemotherapy), or is a high-risk solid organ (lung, heart-lung, heart, pancreas, liver, kidney, small bowel) transplant patient **OR** B. BOTH of the following: 1. The patient has a serious infection caused by Scedosporium or Zygomycetes **AND** 2. The patient has continued indicators of active disease (e.g., continued radiologic findings, positive cultures, positive serum galactomannan assay for Aspergillus) **OR** C. BOTH of the following: 1. The patient has a diagnosis of invasive Aspergillus **AND** 2. The patient has continued indicators of active disease (e.g., continued radiologic findings, positive cultures, positive serum galactomannan assay for Aspergillus) **OR** D. BOTH of the following: 1. The patient has another FDA approved indication or another indication that is supported in compendia for the requested agent and route of administration **AND** 2. The prescriber has submitted information supporting continued use of the requested agent for the requested indication **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS, or DrugDex 1 or 2a level of evidence **Length of Approval:** 6 months
Vfend	**Initial Evaluation** **Vfend (voriconazole)** will be approved when ALL of the following are met: 1. ONE of the following: A. The patient has a diagnosis of invasive Aspergillus **OR** B. BOTH of the following:

Module	Clinical Criteria for Approval
	1. The requested agent is being prescribed for prophylaxis of invasive Aspergillus or Candida **AND** 2. The patient is severely immunocompromised (e.g., hematopoietic stem cell transplant (HSCT) recipients, a hematologic malignancy with prolonged neutropenia from chemotherapy), or is a high-risk solid organ (lung, heart-lung, heart, pancreas, liver, kidney, small bowel) transplant patient **OR** C. The patient has a diagnosis of esophageal candidiasis, candidemia, or other deep tissue Candida infection AND ONE of the following: 1. The patient has tried and had an inadequate response to fluconazole **OR** 2. The patient has an intolerance or hypersensitivity to fluconazole **OR** 3. The patient has an FDA labeled contraindication to fluconazole **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 fluconazole 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 a serious infection caused by Scedosporium or Fusarium species **OR** E. The patient has a diagnosis of blastomycosis AND ONE of the following: 1. The patient has tried and had an inadequate response to itraconazole **OR** 2. The patient has an intolerance or hypersensitivity to itraconazole **OR** 3. The patient has an FDA labeled contraindication to itraconazole **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 itraconazole 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** F. The patient has another FDA approved indication for the requested agent and route of administration **OR** G. 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, 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 patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS, or DrugDex 1 or 2a level of evidence

Module	Clinical Criteria for Approval
	Length of Approval: 1 month for esophageal candidiasis, 6 months for all other indications **Renewal Evaluation** **Vfend (voriconazole)** 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 review process **AND** 2. ONE of the following: A. BOTH of the following: 1. The patient has a diagnosis of invasive Aspergillus **AND** 2. The patient has continued indicators of active disease (e.g., continued radiologic findings, positive cultures, positive serum galactomannan assay for Aspergillus) **OR** B. BOTH of the following: 1. The requested agent is being prescribed for prophylaxis of invasive Aspergillus or Candida **AND** 2. The patient is severely immunocompromised (e.g., hematopoietic stem cell transplant (HSCT) recipients, a hematologic malignancy with prolonged neutropenia from chemotherapy), or is a high-risk solid organ (lung, heart-lung, heart, pancreas, liver, kidney, small bowel) transplant patient **OR** C. BOTH of the following: 1. The patient has a diagnosis of esophageal candidiasis, candidemia, or other deep tissue Candida infection **AND** 2. The patient has continued indicators of active disease (e.g., continued radiologic findings, positive cultures, positive serum galactomannan assay for Aspergillus) **OR** D. BOTH of the following: 1. The patient has a serious infection caused by Scedosporium or Fusarium species **AND** 2. The patient has continued indicators of active disease (e.g., continued radiologic findings, positive cultures, positive serum galactomannan assay for Aspergillus) **OR** E. BOTH of the following: 1. The patient has a diagnosis of blastomycosis **AND** 2. The patient has continued indicators of active disease (e.g., continued radiologic findings, positive cultures, positive serum galactomannan assay for Aspergillus) **OR** F. BOTH of the following: 1. The patient has another FDA approved indication or another indication that is supported in compendia for the requested agent and route of administration **AND** 2. The prescriber has submitted information supporting continued use of the requested agent for the intended diagnosis **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS, or DrugDex 1 or 2a level of evidence **Length of Approval:** 1 month for esophageal candidiasis, 6 months for all other indications
Vivjoa	**Vivjoa (oteseconazole)** will be approved when BOTH of the following are met: 1. ONE of the following: A. ALL of the following: 1. The patient has a diagnosis of recurrent vulvovaginal candidiasis **AND** 2. The patient has experienced greater than or equal to 3 episodes of vulvovaginal candidiasis (VVC) in a 12 months period **AND** 3. ONE of the following: A. The patient has tried and had an inadequate response to fluconazole **OR** B. The patient has an intolerance or hypersensitivity to fluconazole **OR** C. The patient has an FDA labeled contraindication to fluconazole **OR**

Module	Clinical Criteria for Approval
	D. The patient will be using fluconazole as part of the combination dosing regimen (fluconazole with Vivjoa) for the current infection **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 fluconazole 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 approved 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. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS, or DrugDex 1 or 2a level of evidence **Length of Approval:** 4 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Brexafemme, Vivjoa	**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. The prescriber has provided information in support of therapy with a higher dose for the requested indication **Length of Approval**: Brexafemme: 3 months for treatment of vulvovaginal candidiasis 6 months for recurrent vulvovaginal candidiasis Vivjoa: 4 months

• Program Summary: Carbaglu (carglumic acid)

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

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. ALL of the following: 1. The patient has a diagnosis of N-acetylglutamate synthase (NAGS) deficiency confirmed by enzyme analysis (via liver biopsy) OR genetic testing **AND** 2. The patient has a diagnosis of hyperammonemia AND ALL of the following: A. The patient has elevated ammonia levels according to the patient's age [Neonate: plasma ammonia level 150 µmol/L (> 260 µg/dl) or higher; Older child or adult: plasma ammonia level > 100 µmol/L (175 µg/dl)] **AND** B. The patient has a normal anion gap **AND** C. The patient has a normal blood glucose level **AND** 3. The patient is unable to maintain a plasma ammonia level within the normal range with the use of a protein restricted diet and, when clinically appropriate, essential amino acid supplementation **OR** B. ALL of the following: 1. ONE of the following: A. The patient has a diagnosis of methylmalonic acidemia (MMA) **OR** B. The patient has a diagnosis of propionic acidemia (PA, PROP) **AND** 2. The requested drug will be used as adjunctive therapy to standard of care for the treatment of acute hyperammonemia **AND** 3. The patient was hospitalized with a plasma ammonia level ≥70 µmol/L **AND** 2. ONE of the following: A. The requested agent is a generic equivalent **OR** B. The patient has tried and had an inadequate response to the generic equivalent **OR** C. The patient has an intolerance or hypersensitivity to the generic equivalent that is not expected to occur with the brand agent **OR** D. The patient has an FDA labeled contraindication to the generic equivalent that is not expected to occur with the brand agent **OR** E. The prescriber has provided information to support the use of the requested brand agent over the generic equivalent **OR** F. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on the requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** G. The prescriber has provided documentation that the generic equivalent 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. The prescriber is a specialist in the area of the patient's diagnosis (e.g., nephrologist, metabolic disorders) 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**

Module	Clinical Criteria for Approval
	5. The requested quantity (dose) is within FDA labeled dosing for the requested indication **Length of Approval:** Methylmalonic acidemia (MMA) or propionic acidemia (PA): 1 month NAGS deficiency: 12 months **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process (note Carbaglu for methylmalonic acidemia [MMA] or propionic acidemia [PA] should always be reviewed under Initial Evaluation) **AND** 2. The patient has had clinical benefit with the requested agent as evidenced by plasma ammonia level within the normal range **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., nephrologist, metabolic disorders) 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 requested quantity (dose) is within FDA labeled dosing for the requested indication **Length of Approval:** 12 months

• Program Summary: Cholestasis Pruritus

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

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Final Module	Target Agent GPI	Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Targeted NDCs When Exclusions Exist	Final Age Limit	Preferred Status	Effective Date
	523500600001	Bylvay	odevixibat cap	1200 MCG; 400 MCG	M; N; O; Y				
	523500600068	Bylvay (pellets)	odevixibat pellets cap sprinkle	200 MCG; 600 MCG	M; N; O; Y				
	523500501020	Livmarli	maralixibat chloride oral soln	9.5 MG/ML	M; N; O; Y				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Bylvay	**Initial Evaluation** **Bylvay (odevixibat)** will be approved when ALL of the following are met: 1. ONE of the following: A. BOTH of the following: 1. The patient has a diagnosis of progressive familial intrahepatic cholestasis (PFIC) with pruritus (medical records required) **AND** 2. The patient does NOT have a diagnosis of PFIC2 with ABCB11 variants resulting in non-functional or complete absence of bile salt export pump protein (BSEP-3) **OR** B. The patient has a diagnosis of Alagille syndrome with pruritus (medical records required) **OR** C. The patient has another FDA approved indication for the requested agent and route of

Module	Clinical Criteria for Approval
	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 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. ONE of the following: A. The patient has tried and had an inadequate response to a standard cholestasis pruritus treatment agent (i.e., ursodiol, cholestyramine, naltrexone, or rifampicin) **OR** B. The patient has an intolerance or hypersensitivity to therapy with a standard cholestasis pruritus treatment agent (i.e., ursodiol, cholestyramine, naltrexone, or rifampicin) **OR** C. The patient has an FDA labeled contraindication to ALL standard cholestasis pruritus treatment agents (i.e., ursodiol, cholestyramine, naltrexone, and rifampicin) **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 standard cholestasis pruritus treatment agents (i.e., ursodiol, cholestyramine, naltrexone, and rifampicin) 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's INR is less than 1.4 **AND** 5. The patient has an ALT and total bilirubin that is less than 10-times the upper limit of normal **AND** 6. The patient has a serum bile acid concentration above the upper limit of normal **AND** 7. ONE of the following: A. The patient has NOT had a liver transplant **OR** B. The patient has had a liver transplant and the prescriber has provided information in support of using the requested agent post liver transplant **AND** 8. 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** 9. The patient will NOT be using the requested agent in combination with another Ileal Bile Acid Transport (IBAT) inhibitor agent (e.g., Livmarli) **AND** 10. The requested quantity (dose) is within FDA labeled dosing for the requested indication **Compendia Allowed:** AHFS, or DrugDex 1 or 2a level of evidence **Length of Approval:** 12 months **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. The patient has had clinical benefit with the requested agent **AND**

Module	Clinical Criteria for Approval
	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 will NOT be using the requested agent in combination with another Ileal Bile Acid Transport (IBAT) inhibitor agent (e.g., Livmarli) **AND** 5. The requested quantity (dose) is within FDA labeled dosing for the requested indication **Length of Approval:** 12 months
Livmarli	**Initial Evaluation** **Livmarli (maralixibat)** will be approved when ALL of the following are met: 1. ONE of the following: A. The patient has a diagnosis of Alagille syndrome with pruritus (medical records required) **OR** B. The patient has another FDA approved 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 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. ONE of the following: A. The patient has tried and had an inadequate response to a standard cholestasis pruritus treatment agent (i.e., ursodiol, cholestyramine, naltrexone, or rifampicin) **OR** B. The patient has an intolerance or hypersensitivity to therapy with a standard cholestasis pruritus treatment agent (i.e., ursodiol, cholestyramine, naltrexone, or rifampicin) **OR** C. The patient has an FDA labeled contraindication to ALL standard cholestasis pruritus treatment agents (i.e., ursodiol, cholestyramine, naltrexone, and rifampicin) **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 standard cholestasis pruritus treatment agents (i.e., ursodiol, cholestyramine, naltrexone, and rifampicin) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 4. The patient does NOT have decompensated cirrhosis **AND** 5. The patient has NOT had surgical interruption of the enterohepatic circulation of bile acid **AND** 6. The patient has a serum bile acid concentration above the upper limit of normal **AND** 7. ONE of the following: A. The patient has NOT had a liver transplant **OR** B. The patient has had a liver transplant and the prescriber has provided information in support of using the requested agent post liver transplant **AND** 8. 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** 9. The patient will NOT be using the requested agent in combination with another Ileal Bile Acid Transport (IBAT) inhibitor agent (e.g., Bylvay) **AND**

Module	Clinical Criteria for Approval
	10. The requested quantity (dose) is within FDA labeled dosing for the requested indication **Compendia Allowed:** AHFS, or DrugDex 1 or 2a level of evidence **Length of Approval:** 12 months **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **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., gastroenterologist, hepatologist) 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 Ileal Bile Acid Transport (IBAT) inhibitor agent (e.g., Bylvay) **AND** 5. The requested quantity (dose) is within FDA labeled dosing for the requested indication **Length of Approval:** 12 months

• Program Summary: Cibinqo (abrocitinib)

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

POLICY AGENT SUMMARY QUANTITY LIMIT

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

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. Information has been provided that indicates the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR** 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 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**

Module	Clinical Criteria for Approval
	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 of greater than or equal to 16 **OR** D. The patient has an investigator Global Assessment (IGA) score of 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 mid- potency topical steroid used in the treatment of AD **OR** B. The patient has an intolerance or hypersensitivity to at least a mid- potency topical steroid used in the treatment of AD **OR** C. The patient has an FDA labeled contraindication to ALL mid-, high-, and super-potency topical steroids used in the treatment of AD **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on the requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL mid-, high-, and super-potency topical steroids used in the treatment of AD cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 3. ONE of the following: A. The patient has tried and had an inadequate response to a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) used in the treatment of AD **OR** B. The patient has an intolerance or hypersensitivity to a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) used in the treatment of AD **OR** C. The patient has an FDA labeled contraindication to ALL topical calcineurin inhibitors used in the treatment of AD **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on the requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL topical calcineurin inhibitors used in the treatment of AD cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 4. ONE of the following**:**

Module	Clinical Criteria for Approval
	A. The patient has tried and had an inadequate response to a systemic immunosuppressant, including a biologic, used in the treatment of AD **OR** B. The patient has an intolerance or hypersensitivity to therapy with systemic immunosuppressants, including a biologic, used in the treatment of AD **OR** C. The patient has an FDA labeled contraindication to ALL systemic immunosuppressants, including biologics, used in the treatment of AD **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on the requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL systemic immunosuppressants, including biologics, 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** 5. ONE of the following: A. The patient has tried and had an inadequate response to Dupixent for the treatment of AD **OR** B. The patient has an intolerance or hypersensitivity to Dupixent **OR** C. The patient has an FDA labeled contraindication to Dupixent **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 Dupixent cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 6. ONE of the following: A. The patient has tried and had an inadequate response to Rinvoq used for the treatment of AD **OR** B. The patient has an intolerance or hypersensitivity to Rinvoq **OR** C. The patient has an FDA labeled contraindication to Rinvoq **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 Rinvoq cannot be used due to

Module	Clinical Criteria for Approval
	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. ONE of the following: A. The patient has tried and had an inadequate response to Adbry used for the treatment of AD **OR** B. The patient has an intolerance or hypersensitivity to Adbry **OR** C. The patient has an FDA labeled contraindication to Adbry **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 Adbry 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** 8. The prescriber has assessed 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) **AND** 9. The patient will be using standard maintenance therapy (e.g., topical emollients, good skin care practices) in combination with the requested agent **OR** D. The patient has another FDA approved indication for the requested agent and route of administration **OR** E. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND** 2. If the patient has an FDA 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 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. The prescriber has provided information in support of combination therapy (submitted copy required, e.g., clinical trials, phase III studies, guidelines required) **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **Length of Approval**: 6 months

Module	Clinical Criteria for 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 **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. The prescriber has provided information in support of combination therapy (submitted copy required, e.g., clinical trials, phase III studies, guidelines required) **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed**: AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **Length of Approval**: 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	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

Module	Clinical Criteria for Approval
	strength that does not exceed the program quantity limit **Length of Approval**: Initial - 6 months Renewal - 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) 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) 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)

Contraindicated as Concomitant Therapy
Simponi (golimumab) Simponi ARIA (golimumab) Skyrizi (risankizumab-rzaa) Sotyktu (deucravacitinib) Stelara (ustekinumab) Taltz (ixekizumab) Tezspire (tezepelumab-ekko) Tremfya (guselkumab) Truxima (rituximab-abbs) Tysabri (natalizumab) Xeljanz (tofacitinib) Xeljanz XR (tofacitinib extended release) Xolair (omalizumab) Yuflyma (adalimumab-aaty) Yusimry (adalimumab-aqvh) Zeposia (ozanimod)

• Program Summary: CMV (cytomegalovirus)

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
12200050000320	Livtencity	Maribavir Tab	200 MG	120	Tablets	30	DAYS					
122000450003	Prevymis	letermovir tab	240 MG; 480 MG	200	Tablets	365	DAYS	Quantity limit is cumulative at GPI 12				

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Livtencity	**Quantity limit for Livtencity** will be approved for an increased quantity when **ALL** of the following are met: 1. The patient has a post-transplant CMV infection/disease that is refractory to treatment (with or without genotypic resistance) with ganciclovir, valganciclovir, cidofovir or foscarnet **AND** 2. The patient will NOT be using the requested agent in combination with ganciclovir and/or valganciclovir for the requested indication **AND** 3. The prescriber has provided information in support of therapy with a higher dose and/or and increased quantity for the requested indication **Length of Approval:** 12 months
Prevymis	**Quantity limit for Prevymis** will be approved for an increased quantity and/or an extended duration when **BOTH** of the following are met: 1. ONE of the following: A. The patient has had an additional allogeneic hematopoietic stem cell transplant (HSCT) and

Module	Clinical Criteria for Approval
	requires initiation of PREVYMIS **OR** B. The patient has had an additional kidney transplant and is at high risk (Donor CMV seropositive/Recipient CMV seronegative [D+/R-]) and requires initiation of PREVYMIS **OR** C. The prescriber has provided information in support of therapy with a higher dose and/or a longer duration for the requested indication **AND** 2. 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:** Additional transplant: 200 tablets/365 days Higher quantity/longer duration: Approve quantity requested/365 days

• Program Summary: Interleukin-4 (IL-4) Inhibitors

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
9027302000D215	Dupixent	Dupilumab Subcutaneous Soln Pen-injector	200 MG/1.14ML	2	Pens	28	DAYS			
9027302000D220	Dupixent	Dupilumab Subcutaneous Soln Pen-injector 300 MG/2ML	300 MG/2ML	4	Pens	28	DAYS			
9027302000E510	Dupixent	Dupilumab Subcutaneous Soln Prefilled Syringe	100 MG/0.67ML	2	Syringes	28	DAYS			
9027302000E515	Dupixent	Dupilumab Subcutaneous Soln Prefilled Syringe 200 MG/1.14ML	200 MG/1.14ML	2	Syringes	28	DAYS			
9027302000E520	Dupixent	Dupilumab Subcutaneous Soln Prefilled Syringe 300 MG/2ML	300 MG/2ML	4	Syringes	28	DAYS			

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The requested agent is eligible for continuation of therapy AND ONE of the following: **Agents Eligible for Continuation of Therapy** All target agents are eligible for continuation of therapy 1. Information has been provided that indicates the patient has been treated with the

Module	Clinical Criteria for Approval
	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 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 of greater than or equal to 16 **OR** D. The patient has an Investigator Global Assessment (IGA) score of greater than or equal to 3 **AND** 2. ONE of the following: A. The patient has tried and had an inadequate response to an oral systemic immunosuppressant (e.g., methotrexate, azathioprine, mycophenolate mofetil, cyclosporine) **OR** B. The patient has an intolerance or hypersensitivity to an oral systemic immunosuppressant **OR** C. The patient has tried and had an inadequate response to BOTH at least a mid-potency topical steroid AND a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) **OR** D. The patient has an intolerance or hypersensitivity to BOTH at least a mid-potency topical steroid AND a topical calcineurin inhibitor **OR** E. The patient has an FDA labeled contraindication to ALL oral systemic immunosuppressants, mid-, high-, and super-potency topical steroids AND topical calcineurin inhibitors **OR** F. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** G. The prescriber has provided documentation that ALL oral systemic immunosuppressants, mid-, high-, and super-potency topical steroids AND topical calcineurin inhibitors cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 3. The prescriber has assessed 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)**AND** 4. The patient will be using standard maintenance therapy (e.g., topical emollients, good skin care practices) in combination with the requested agent **OR** C. The patient has a diagnosis of moderate to severe asthma AND ALL of the following 1. ONE of the following: A. The patient has eosinophilic type asthma AND ONE of the following: 1. The patient has a baseline (prior to therapy with the requested agent) blood eosinophilic count of 150 cells/microliter or higher while on high-

Module	Clinical Criteria for Approval
	dose inhaled corticosteroids or daily oral corticosteroids **OR** 2. The patient has a fraction of exhaled nitric oxide (FeNO) of 20 parts per billion or higher while on high-dose inhaled corticosteroids or daily oral corticosteroids **OR** 3. The patient has sputum eosinophils 2% or higher while on high-dose inhaled corticosteroids or daily oral corticosteroids **OR** B. The patient has oral corticosteroid dependent type asthma **AND** 2. The patient has a history of uncontrolled asthma while on asthma control therapy as demonstrated by ONE of the following: A. Frequent severe asthma exacerbations requiring two or more courses of systemic corticosteroids (steroid burst) within the past 12 months **OR** B. Serious asthma exacerbations requiring hospitalization, mechanical ventilation, or visit to the emergency room or urgent care within the past 12 months **OR** C. Controlled asthma that worsens when the doses of inhaled and/or systemic corticosteroids are tapered **OR** D. The patient has baseline (prior to therapy with the requested agent) Forced Expiratory Volume (FEV1) that is less than 80% of predicted **AND** 3. ONE of the following: A. The patient is NOT currently being treated with the requested agent AND is currently treated with a maximally tolerated inhaled corticosteroid **OR** B. The patient is currently being treated with the requested agent AND ONE of the following: 1. Is currently treated with an inhaled corticosteroid that is adequately dosed to control symptoms **OR** 2. Is currently treated with a maximally tolerated inhaled corticosteroid **OR** C. The patient has an intolerance or hypersensitivity to inhaled corticosteroid therapy **OR** D. The patient has an FDA labeled contraindication to ALL inhaled corticosteroids **AND** 4. ONE of the following: A. The patient is currently being treated with ONE of the following: 1. A long-acting beta-2 agonist (LABA) **OR** 2. A leukotriene receptor antagonist (LTRA) **OR** 3. Long-acting muscarinic antagonist (LAMA) **OR** 4. Theophylline **OR** B. The patient has an intolerance or hypersensitivity to therapy with a LABA, LTRA, LAMA, or theophylline **OR** C. The patient has an FDA labeled contraindication to ALL LABA, LTRA, LAMA, AND theophylline therapies **AND** 5. The patient will continue asthma control therapy (e.g., ICS, ICS/LABA, LTRA, LAMA, theophylline) in combination with the requested agent **OR** D. The patient has a diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP) AND ALL of the following: 1. The patient has at least TWO of the following symptoms consistent with chronic rhinosinusitis (CRS): A. Nasal discharge (rhinorrhea or post-nasal drainage) B. Nasal obstruction or congestion C. Loss or decreased sense of smell (hyposmia) D. Facial pressure or pain **AND** 2. The patient has had symptoms consistent with chronic rhinosinusitis (CRS) for at least 12 consecutive weeks **AND**

Module	Clinical Criteria for Approval
	3. There is information indicating the patient's diagnosis was confirmed by ONE of the following: A. Anterior rhinoscopy or endoscopy **OR** B. Computed tomography (CT) of the sinuses **AND** 4. ONE of the following: A. ONE of the following: 1. The patient had an inadequate response to sinonasal surgery **OR** 2. The patient is NOT a candidate for sinonasal surgery **OR** B. ONE of the following: 1. The patient has tried and had an inadequate response to oral systemic corticosteroids **OR** 2. The patient has an intolerance or hypersensitivity to therapy with oral systemic corticosteroids **OR** 3. The patient has an FDA labeled contraindication to ALL oral systemic corticosteroids **AND** 5. ONE of the following: A. The patient has tried and had an inadequate response to intranasal corticosteroids (e.g., fluticasone, Sinuva) **OR** B. The patient has an intolerance or hypersensitivity to therapy with intranasal corticosteroids (e.g., fluticasone, Sinuva) **OR** C. The patient has an FDA labeled contraindication to ALL intranasal corticosteroids **AND** 6. BOTH of the following: A. The patient is currently treated with standard nasal polyp maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids) **AND** B. The patient will continue standard nasal polyp maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids) in combination with the requested agent **OR** E. The patient has a diagnosis of eosinophilic esophagitis (EoE) AND BOTH of the following: 1. The patient's diagnosis was confirmed by ALL of the following: A. Chronic symptoms of esophageal dysfunction **AND** B. Greater than or equal to 15 eosinophils per high-power field on esophageal biopsy **AND** C. Other causes that may be responsible for or contributing to symptoms and esophageal eosinophilia have been ruled out **AND** 2. ONE of the following: A. The patient has tried and had an inadequate response to ONE standard corticosteroid therapy for EoE (i.e., budesonide suspension, fluticasone MDI swallowed) **OR** B. The patient has an intolerance or hypersensitivity to standard corticosteroid therapy for EoE **OR** C. The patient has an FDA labeled contraindication to standard corticosteroid therapy for EoE **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 standard corticosteroid

Module	Clinical Criteria for Approval
	therapy for EoE 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** F. The patient has a diagnosis of prurigo nodularis (PN) and BOTH of the following: 1. The patient has ALL of the following features associated with PN: A. Presence of firm, nodular lesions **AND** B. Pruritus that has lasted for at least 6 weeks **AND** C. History and/or signs of repeated scratching, picking, or rubbing **AND** 2. ONE of the following: A. The patient has tried and had an inadequate response to at least a mid-potency topical steroid **OR** B. The patient has an intolerance or hypersensitivity to therapy with at least a mid-potency topical steroid **OR** C. The patient has an FDA labeled contraindication to ALL mid-, high-, and super-potency topical steroids **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 mid-, high-, and super-potency topical steroids 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** G. The patient has another FDA approved indication for the requested agent and route of administration **OR** H. 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 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., atopic dermatitis -dermatologist, allergist, immunologist; asthma -allergist, immunologist, pulmonologist; CRSwNP -otolaryngologist, allergist, pulmonologist) 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. The prescriber has provided information in support of combination therapy (submitted copy required, e.g., clinical trials, phase III studies, guidelines required) **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent

Module	Clinical Criteria for Approval
	Compendia Allowed: AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **Length of Approval:** 6 months **Note:** Please approve initial loading dose for asthma, atopic dermatitis, and prurigo nodularis only • 300 mg strength requested: 600 mg (two 300 mg injections) followed by maintenance dose • 200 mg strength requested: 400 mg (two 200 mg injections) followed by maintenance dose 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 **AND** 2. ONE of the following: A. The patient has a diagnosis of moderate-to-severe atopic dermatitis (AD) 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 Assessnent (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 of moderate to severe asthma AND BOTH of the following: 1. The patient has had improvements or stabilization with the requested agent from baseline (prior to therapy with the requested agent) as indicated by ONE of the following: A. The patient has had an increase in percent predicted Forced Expiratory Volume (FEV_1) **OR** B. The patient has had a decrease in the dose of inhaled corticosteroids required to control the patient's asthma **OR** C. The patient has had a decrease in need for treatment with systemic corticosteroids due to exacerbations of asthma **OR** D. The patient has had a decrease in number of hospitalizations, need for mechanical ventilation, or visits to urgent care or emergency room due to exacerbations of asthma **AND** 2. The patient is currently treated and is compliant with asthma control therapy [e.g., inhaled corticosteroids, ICS/long-acting beta-2 agonist (LABA), leukotriene receptor antagonist (LTRA), long-acting muscarinic antagonist (LAMA), theophylline] **OR** C. The patient has a diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP) AND BOTH of the following: 1. The patient has had clinical benefit with the requested agent **AND** 2. The patient will continue standard nasal polyp maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids) in combination with the requested agent **OR** D. The patient has a diagnosis other than moderate-to-severe atopic dermatitis (AD), moderate to severe asthma, or chronic rhinosinusitis with nasal polyposis (CRSwNP) AND has had clinical

Module	Clinical Criteria for Approval
	benefit with the requested agent **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., atopic dermatitis -dermatologist, allergist, immunologist; asthma -allergist, immunologist, pulmonologist; CRSwNP -otolaryngologist, allergist, pulmonologist) 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. The prescriber has provided information in support of combination therapy (submitted copy required, e.g., clinical trials, phase III studies, guidelines required) **AND** 5. The patient does NOT have an FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit criteria

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity Limits 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, or the compendia supported 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 **Compendia Allowed:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **Length of Approval**: 6 months for Initial; 12 months for Renewal

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) Cibinqo (abrocitinib) Cimzia (certolizumab)

Contraindicated as Concomitant Therapy
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)
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)
Simponi (golimumab)
Simponi ARIA (golimumab)
Skyrizi (risankizumab-rzaa)
Sotyktu (deucravacitinib)
Stelara (ustekinumab)
Taltz (ixekizumab)
Tezspire (tezepelumab-ekko)
Tremfya (guselkumab)
Truxima (rituximab-abbs)
Tysabri (natalizumab)
Xeljanz (tofacitinib)
Xeljanz XR (tofacitinib extended release)
Xolair (omalizumab)
Yuflyma (adalimumab-aaty)
Yusimry (adalimumab-aqvh)
Zeposia (ozanimod)

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

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
9027308045E520	Adbry	Tralokinumab-ldrm Subcutaneous Soln Prefilled Syr	150 MG/ML	4	Syringes	28	DAYS		09-01-2022	

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The requested agent is eligible for continuation of therapy AND ONE of the following: **Agents Eligible for Continuation of Therapy** All target agents are eligible for continuation of therapy 1. Information has been provided that indicates the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR** 2. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR** B. The patient has a diagnosis of 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 of greater than or equal to 3 **AND** 2. ONE of the following: A. The patient has tried and had an inadequate response to an oral systemic immunosuppressant (e.g., methotrexate, azathioprine, mycophenolate mofetil, cyclosporine) used for the treatment of AD **OR** B. The patient has an intolerance or hypersensitivity to an oral systemic immunosuppressant **OR** C. The patient has tried and had an inadequate response to BOTH at least a mid-potency topical steroid AND a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) **OR** D. The patient has an intolerance or hypersensitivity to BOTH at least a mid-potency topical steroid AND a topical calcineurin inhibitor **OR** E. The patient has an FDA labeled contraindication to ALL oral systemic immunosuppressants, mid-, high-, super-potency topical steroids, AND topical calcineurin inhibitors **OR**

Module	Clinical Criteria for Approval
	F. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on the requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** G. The prescriber has provided documentation that ALL oral systemic immunosuppressants, mid-, high-, super-potency topical steroids, AND topical calcineurin inhibitors cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 3. The prescriber has assessed 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) **AND** 4. The patient will be using standard maintenance therapy (e.g., topical emollients, good skin care practices) in combination with the requested agent **OR** C. The patient has another FDA approved 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 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. 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. The prescriber has provided information in support of 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. The prescriber has provided information in support of combination therapy (submitted copy required, e.g., clinical trials, phase III studies, guidelines required) **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent

Module	Clinical Criteria for Approval
	Compendia Allowed: AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **Length of Approval**: 6 months **Note**: Approve Adbry subcutaneous loading dose for 1 month, then maintenance dose can be approved for the remainder of 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 **AND** 2. ONE of the following: A. The patient has a diagnosis of moderate-to-severe atopic dermatitis AND BOTH of the following: 1. The patient has had a reduction or stabilization from baseline (prior to therapy with the requested agent) of ONE of the following: A. Affected body surface area **OR** B. Flares **OR** C. Pruritus, erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification **OR** D. A decrease in the Eczema Area and Severity Index (EASI) score **OR** E. A decrease in the Investigator Global Assessment (IGA) score **AND** 2. The patient will continue standard maintenance therapies (e.g., topical emollients, good skin care practices) in combination with the requested agent **OR** B. The patient has a diagnosis other than moderate-to-severe atopic dermatitis AND has had clinical benefit with the requested agent **AND** 3. ONE of the following: A. The patient is initiating therapy with the requested agent **OR** B. The patient has been treated with the requested agent for less than 16 consecutive weeks **OR** C. The patient has been treated with the requested agent for at least 16 consecutive weeks **AND** ONE of the following: 1. The patient weighs less than 100 kg and ONE of the following: A. The patient has achieved clear or almost clear skin AND the patient's dose will be reduced to 300 mg every 4 weeks **OR** B. The patient has NOT achieved clear or almost clear skin **OR** C. The prescriber has provided information in support of 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. The prescriber has provided information in support of combination therapy (submitted copy required, e.g., clinical trials, phase III studies, guidelines required) **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent

Module	Clinical Criteria for Approval
	Compendia Allowed: AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **Length of Approval**: 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT 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. 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 **Length of Approval**: Initial approval - 6 months Renewal approval - 12 months **Note**: Approve Adbry subcutaneous loading dose for 1 month, then maintenance dose can be approved for the remainder of 6 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) 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)

Contraindicated as Concomitant Therapy
Ilaris (canakinumab) Ilumya (tildrakizumab-asmn) Inflectra (infliximab-dyyb) Infliximab Kevzara (sarilumab) Kineret (anakinra) Litfulo (ritlecitinib) Nucala (mepolizumab) Olumiant (baricitinib) 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) Simponi (golimumab) Simponi ARIA (golimumab) Skyrizi (risankizumab-rzaa) Sotyktu (deucravacitinib) Stelara (ustekinumab) Taltz (ixekizumab) Tezspire (tezepelumab-ekko) Tremfya (guselkumab) Truxima (rituximab-abbs) Tysabri (natalizumab) Xeljanz (tofacitinib) Xeljanz XR (tofacitinib extended release) Xolair (omalizumab) Yusimry (adalimumab-aqvh) Zeposia (ozanimod)

• Program Summary: Isturisa

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
30022060600320	Isturisa	Osilodrostat Phosphate Tab 1 MG	1 MG	240	Tablets	30	DAYS			
30022060600340	Isturisa	Osilodrostat Phosphate Tab 10 MG	10 MG	180	Tablets	30	DAYS			
30022060600330	Isturisa	Osilodrostat Phosphate Tab 5 MG	5 MG	360	Tablets	30	DAYS			

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent** will be approved when ALL of the following are met: 1. The patient has a diagnosis of Cushing's disease **AND** 2. ONE of the following: A. The patient had an inadequate response to pituitary surgery **OR** B. The patient is NOT a candidate for pituitary surgery **AND** 3. The patient's disease is persistent or recurrent as evidenced by ONE of the following: A. The patient has a mean of three 24 hour urine free cortisol (UFC) >1.3 times the upper limit of normal **OR** B. Morning plasma adrenocorticotropic hormone (ACTH) above the lower limit of normal **AND** 4. ONE of the following: A. The patient has tried and had an inadequate response to at least ONE of the following conventional agents: 1. Mifepristone 2. Signifor/Signifor LAR (pasireotide) 3. Recorlev (levoketoconazole) 4. Cabergoline 5. Metyrapone 6. Lysodren (mitotane) **OR** B. The patient has an intolerance or hypersensitivity to mifepristone, pasireotide, or levoketoconazole **OR** C. The patient has an FDA labeled contraindication to mifepristone, pasireotide, and levoketoconazole **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 cabergoline, pasireotide, and mifepristone) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 5. ONE of the following: A. The patient has tried and had an inadequate response to ketoconazole tablets **OR** B. The patient has an intolerance or hypersensitivity to ketoconazole tablets **OR** C. The patient has an FDA labeled contraindication to ketoconazole tablets **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 ketoconazole tablets 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

Module	Clinical Criteria for Approval
	daily activities or cause physical or mental harm **AND** 6. 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** 7. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 8. The patient will NOT be using the requested agent in combination with glucocorticoid replacement therapy **AND** 9. 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** 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 **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., endocrinologist) 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 glucocorticoid replacement therapy **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 **Length of Approval:** Initial: 6 months; Renewal: 12 months

• Program Summary: Ivermectin - *Discontinued*

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

This program will be discontinued, effective 12/1/2023

• Program Summary: Jynarque

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
30454060000320	Jynarque	tolvaptan tab	15 MG	60	Tablets	30	DAYS	59148008213		
30454060000330	Jynarque	tolvaptan tab	30 MG	30	Tablets	30	DAYS	59148008313		
3045406000B710	Jynarque	Tolvaptan Tab Therapy Pack 15 MG	15 MG	56	Tablets	28	DAYS			
3045406000B720	Jynarque	Tolvaptan Tab Therapy Pack 30 & 15 MG	30 & 15 MG	56	Tablets	28	DAYS			
3045406000B725	Jynarque	Tolvaptan Tab Therapy Pack 45 & 15 MG	45 & 15 MG	56	Tablets	28	DAYS			
3045406000B735	Jynarque	Tolvaptan Tab Therapy Pack 60 & 30 MG	60 & 30 MG	56	Tablets	28	DAYS			
3045406000B745	Jynarque	Tolvaptan Tab Therapy Pack 90 & 30 MG	90 & 30 MG	56	Tablets	28	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. The patient has a diagnosis of autosomal dominant polycystic kidney disease (ADPKD) and BOTH of the following: A. The patient does not have stage 5 chronic kidney disease (CKD) **AND** B. The patient is not on dialysis **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. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. The patient will NOT be using the requested agent in combination with another tolvaptan agent **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., nephrologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation**

Module	Clinical Criteria for Approval
	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 **AND** 2. The patient has had clinical benefit with the requested agent **AND** 3. The patient will NOT be using the requested agent in combination with another tolvaptan agent **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., nephrologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
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) is greater than 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 **Length of Approval:** 12 months

● Program Summary: Natpara - *Discontinued*

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

This program will be discontinued, effective 12/1/2023

● Program Summary: Opzelura (ruxolitinib)

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
90272060503720	Opzelura	Ruxolitinib Phosphate Cream	1.5 %	1	Tube	30	DAYS			

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. If the request is for use in vitiligo AND vitiligo is NOT restricted from coverage under the patient's benefit **AND** 2. ONE of the following: A. The patient has a diagnosis of mild to moderate atopic dermatitis AND ALL of the following: 1. The patient's affected body surface area (BSA) is less than or equal to 20% **AND** 2. The patient is NOT immunocompromised **AND** 3. ONE of the following: A. The patient has tried and had an inadequate response to at least a low-potency topical corticosteroid **OR** B. The patient has an intolerance or hypersensitivity to therapy with a topical corticosteroid **OR** C. The patient has an FDA labeled contraindication to ALL topical corticosteroids **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 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 **AND** 4. ONE of the following: A. The patient has tried and had an inadequate response to a topical calcineurin inhibitor **OR** B. The patient has an intolerance or hypersensitivity to therapy with a topical calcineurin inhibitor **OR** C. The patient has an FDA labeled contraindication to ALL topical calcineurin inhibitors **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 cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 5. The patient will be using standard maintenance therapy (e.g., topical emollients, good skin care practices) in combination with the requested agent **OR**

Module	Clinical Criteria for Approval
	B. The patient has a diagnosis of nonsegmental vitiligo AND BOTH of the following: 1. The patient's affected body surface area (BSA) is less than or equal to 10% **AND** 2. ONE of the following: A. The patient has vitiligo impacting areas other than the face, neck, or groin AND ONE of the following: 1. The patient has tried and had an inadequate response to at least a potent topical corticosteroid **OR** 2. The patient has an intolerance or hypersensitivity to therapy with a potent topical corticosteroid **OR** 3. The patient has an FDA labeled contraindication to ALL potent topical corticosteroids **OR** 4. The prescriber has provided information indicating why the patient cannot use at least a potent topical corticosteroid for the treatment of vitiligo **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL potent 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** B. The patient has vitiligo on the face, neck, or groin AND ONE of the following: 1. The patient has tried and had an inadequate response to at least a potent topical corticosteroid OR a topical calcineurin inhibitor **OR** 2. The patient has an intolerance or hypersensitivity to therapy with a potent topical corticosteroid OR a topical calcineurin inhibitor **OR** 3. The patient has an FDA labeled contraindication to ALL potent topical corticosteroids AND topical calcineurin inhibitors **OR** 4. The prescriber has provided information indicating why the patient cannot use at least a potent topical corticosteroid OR a topical calcineurin inhibitor for the treatment of vitiligo **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL potent topical corticosteroids AND topical calcineurin inhibitors cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve

Module	Clinical Criteria for Approval
	or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** C. The patient has another FDA approved indication for the requested agent **AND** 3. 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** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist) 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. The prescriber has provided information in support of combination therapy (submitted copy required, e.g., clinical trials, phase III studies, guidelines required) **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 3 months for atopic dermatitis and 6 months for nonsegmental vitiligo 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. ALL of the following: A. The requested quantity (dose) is greater than 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) is greater than the program quantity limit **AND** B. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication **AND** C. The prescriber has provided information in support of therapy with a higher dose for the requested indication **Length of Approval**: 3 months for atopic dermatitis and 6 months for nonsegmental vitiligo

CONTRAINDICATION AGENTS

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

Contraindicated as Concomitant Therapy
Amjevita (adalimumab-atto)
Arcalyst (rilonacept)
Avsola (infliximab-axxq)
Benlysta (belimumab)
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)
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)
Simponi (golimumab)
Simponi ARIA (golimumab)
Skyrizi (risankizumab-rzaa)
Sotyktu (deucravacitinib)
Stelara (ustekinumab)
Taltz (ixekizumab)
Tezspire (tezepelumab-ekko)
Tremfya (guselkumab)
Truxima (rituximab-abbs)
Tysabri (natalizumab)
Xeljanz (tofacitinib)
Xeljanz XR (tofacitinib extended release)
Xolair (omalizumab)
Yusimry (adalimumab-aqvh)

Contraindicated as Concomitant Therapy
Zeposia (ozanimod)

• Program Summary: Oral Pulmonary Arterial Hypertension (PAH)

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
401430800003	Adcirca ; Alyq	tadalafil tab	20 MG	60	Tablets	30	DAYS			
4013405000	Adempas	riociguat tab	0.5 MG; 1 MG; 1.5 MG; 2 MG; 2.5 MG	90	Tablets	30	DAYS			
4016000700	Letairis	ambrisentan tab	10 MG; 5 MG	30	Tablets	30	DAYS			
40143060101825	Liqrev	sildenafil citrate oral susp	10 MG/ML	2	Bottles	30	DAYS			
4016005000	Opsumit	macitentan tab	10 MG	30	Tablets	30	DAYS			
4017008005C110	Orenitram titr kit Month 1	Treprostinil tab er Mo 1 titr kit	0.125 & 0.25 MG	1	Kit	180	DAYS			
4017008005C120	Orenitram titr kit Month 2	Treprostinil tab er Mo 2 titr kit	0.125 & 0.25 MG	1	Kit	180	DAYS			
4017008005C130	Orenitram titr kit Month 3	Treprostinil tab er Mo 3 titr kit	0.125 & 0.25 &1 MG	1	Kit	180	DAYS			
401430601019	Revatio	sildenafil citrate for suspension	10 MG/ML	224	Bottles	30	DAYS			
401430601003	Revatio	sildenafil citrate tab	20 MG	90	Tablets	30	DAYS			
40143080001820	Tadliq	Tadalafil Oral Susp	20 MG/5ML	300	mLs	30	DAYS		09-23-2022	
401600150003	Tracleer	bosentan tab	125 MG; 62.5 MG	60	Tablets	30	DAYS			
401600150073	Tracleer	bosentan tab for oral susp	32 MG	120	Tablets	30	DAYS			
40170080002020	Tyvaso	treprostinil inhalation solution	0.6 MG/ML	7	Packages	28	DAYS	66302020603		
40170080002920	Tyvaso dpi maintenance ki	Treprostinil Inh Powder	16 MCG	112	Cartridges	28	DAYS		06-17-2022	
40170080002930	Tyvaso dpi maintenance ki	Treprostinil Inh Powder	32 MCG	112	Cartridges	28	DAYS		06-17-2022	
40170080002940	Tyvaso dpi maintenance ki	Treprostinil Inh Powder	48 MCG	112	Cartridges	28	DAYS		06-17-2022	
40170080002950	Tyvaso dpi maintenance ki	Treprostinil Inh Powder	64 MCG	112	Cartridges	28	DAYS		06-17-2022	
40170080002960	Tyvaso dpi maintenance ki	Treprostinil Inh Powder	112 x 32MCG & 112 x48MCG	224	Cartridges	28	DAYS		06-17-2022	
40170080002980	Tyvaso dpi	Treprostinil Inh	16 & 32 & 48	252	Cartridge	180	DAYS		06-17-	

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
	titration kit	Powd	MCG		s				2022	
40170080002970	Tyvaso dpi titration kit	Treprostinil Inh Powder	112 x 16MCG & 84 x 32MCG	196	Cartridges	180	DAYS		06-17-2022	
40170080002020	Tyvaso refill	treprostinil inhalation solution	0.6 MG/ML	1	Kit	28	DAYS	66302020602		
40170080002020	Tyvaso starter	treprostinil inhalation solution	0.6 MG/ML	1	Kit	180	DAYS	66302020604		
40170080002020	Tyvaso starter	treprostinil inhalation solution	0.6 MG/ML	1	Kit	180	DAYS	66302020601		
401200700003	Uptravi	selexipag tab	1000 MCG; 1200 MCG; 1400 MCG; 1600 MCG; 200 MCG; 400 MCG; 600 MCG; 800 MCG	60	Tablets	30	DAYS			
40120070000310	Uptravi	selexipag tab	200 MCG	60	Tablets	30	DAYS	66215060206		
40120070000310	Uptravi	selexipag tab	200 MCG	140	Tablets	180	DAYS	66215060214		
4012007000B7	Uptravi titration pack	selexipag tab therapy pack	200 & 800 MCG	1	Pack	180	DAYS			
401700600020	Ventavis	iloprost inhalation solution	10 MCG/ML; 20 MCG/ML	270	Ampules	30				

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. The requested agent is eligible for continuation of therapy AND ONE of the following: **Target Agents Eligible for Continuation of Therapy** All target agents are eligible for continuation of therapy A. Information has been provided that indicates the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR** 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 **AND** 2. The patient has an FDA approved indication for the requested agent **OR** B. The patient has a diagnosis of chronic thromboembolic pulmonary hypertension (CTEPH), WHO Group 4 and ALL of the following: 1. The requested agent is Adempas **AND** 2. The patient's diagnosis has been confirmed by a ventilation-perfusion scan and a confirmatory selective pulmonary angiography **AND** 3. The patient has a mean pulmonary artery pressure of greater than 20 mmHg **AND**

Module	Clinical Criteria for Approval
	4. The patient has a pulmonary capillary wedge pressure less than or equal to 15 mmHg **AND** 5. The patient has a pulmonary vascular resistance greater than or equal to 3 Wood units **AND** 6. ONE of the following: A. The patient is NOT a candidate for surgery **OR** B. The patient has had a pulmonary endarterectomy AND has persistent or recurrent disease **AND** 7. The patient will NOT be using the requested agent in combination with a PDE5 inhibitor (e.g., tadalafil [Adcirca or Cialis] or sildenafil [Revatio or Viagra]) **OR** C. The patient has a diagnosis of pulmonary arterial hypertension (PAH), WHO Group 1 and ALL of the following: 1. The patient's diagnosis has been confirmed by right heart catheterization (medical records required) **AND** 2. The patient's mean pulmonary arterial pressure is greater than 20 mmHg **AND** 3. The patient has a pulmonary capillary wedge pressure less than or equal to 15 mmHg **AND** 4. The patient has a pulmonary vascular resistance greater than or equal to 3 Wood units **AND** 5. The patient's World Health Organization (WHO) functional class is II or greater **AND** 6. If the requested agent is Adcirca, Adempas, Revatio, sildenafil, or tadalafil, the patient will NOT be using the requested agent in combination with a PDE5 inhibitor (e.g., tadalafil [Adcirca or Cialis] or sildenafil [Revatio or Viagra]) **AND** 7. ONE of the following: A. The requested agent will be utilized as monotherapy **OR** B. The requested agent will be utilized as dual therapy that consists of an endothelin receptor antagonist (ERA) plus phosphodiesterase 5 inhibitor (PDE5i) as initial therapy **OR** C. The requested agent will be utilized for add-on therapy to existing monotherapy (dual therapy) [except combo requests for endothelin receptor antagonist (ERA) plus phosphodiesterase 5 inhibitor (PDE5i) for dual therapy], and BOTH of following: 1. The patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy **AND** 2. The requested agent is in a different therapeutic class **OR** D. The requested agent will be utilized for add-on therapy to existing dual therapy (triple therapy) and ALL of the following: 1. The patient is WHO functional class III or IV **AND** 2. ONE of the following: A. A prostanoid has been started as one of the agents in the triple therapy **OR** B. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to ALL prostanoids **AND** 3. The patient has unacceptable or deteriorating clinical status despite established PAH pharmacotherapy **AND** 4. All three agents in the triple therapy are from a different therapeutic class **OR** D. The patient has a diagnosis of pulmonary hypertension associated with interstitial lung disease (PH-ILD, WHO group 3) AND ALL of the following: 1. The requested agent is Tyvaso **AND** 2. The patient's diagnosis has been confirmed by right heart catheterization (medical records required) **AND**

Module	Clinical Criteria for Approval

3. The patient's mean pulmonary arterial pressure is greater than 20 mmHg **AND**
4. The patient has a pulmonary capillary wedge pressure less than or equal to 15 mmHg **AND**
5. The patient has a pulmonary vascular resistance greater than or equal to 3 Wood units **AND**
6. The patient has an FVC less than 70% of predicted **AND**
7. The patient has extensive parenchymal changes on computed tomography (CT) **AND**
8. BOTH of the following:
    A. The patient is currently treated with standard of care therapy for ILD (e.g., Ofev) **AND**
    B. The patient will continue standard of care therapy for ILD (e.g., Ofev) **OR**

E. The patient has another FDA approved indication for the requested agent **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. If the request is for ONE of the following brand agents with an available generic equivalent (listed below), then ONE of the following:

Brand	Generic Equivalent
Revatio (tablet, oral suspension)	sildenafil (tablet, oral suspension)
Adcirca	tadalafil
Tracleer 6.25 mg and 125 mg tablets	bosentan 6.25 mg and 125 mg tablets
Letaris	ambrisentan

    A. The patient's medication history includes the required generic equivalent as indicated by:
        1. Evidence of a paid claim(s) **OR**
        2. The prescriber has stated that the patient has tried the generic equivalent AND the generic equivalent was discontinued due to lack of effectiveness or an adverse event **OR**
    B. The patient has an intolerance or hypersensitivity to the generic equivalent that is not expected to occur with the brand agent **OR**
    C. The patient has an FDA labeled contraindication to the generic equivalent that is not expected to occur with the brand agent **OR**
    D. The prescriber has provided information to support the use of the requested brand agent over the generic equivalent **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 the generic equivalent 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. If the request is for Tadliq, then ONE of the following:
    A. The patient's medication history includes generic tadalafil tablets as indicated by:
        1. Evidence of a paid claim(s) **OR**
        2. The prescriber has stated that the patient has tried generic tadalafil tablets AND generic tadalafil tablets were discontinued due to lack of effectiveness or an adverse event **OR**

Module	Clinical Criteria for Approval
	B. The patient has an intolerance or hypersensitivity to generic tadalafil tablets that is not expected to occur with the requested agent **OR** C. The patient has an FDA labeled contraindication to generic tadalafil tablets that is not expected to occur with the requested agent **OR** D. The prescriber has provided information to support the use of the requested agent over generic tadalafil tablets **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 generic tadalafil tablets cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 5. If the request is for Liqrev, then ONE of the following: A. The patient's medication history includes generic sildenafil oral suspension as indicated by: 1. Evidence of a paid claim(s) **OR** 2. The prescriber has stated that the patient has tried generic sildenafil oral suspension AND generic sildenafil oral suspension was discontinued due to lack of effectiveness or an adverse event **OR** B. The patient has an intolerance or hypersensitivity to generic sildenafil oral suspension that is not expected to occur with the requested agent **OR** C. The patient has an FDA labeled contraindication to generic sildenafil oral suspension that is not expected to occur with the requested agent **OR** D. The prescriber has provided information to support the use of the requested agent over generic sildenafil oral suspension **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 generic sildenafil oral suspension cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 6. The prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist, pulmonologist) 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:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

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 **AND**
2. The patient has had clinical benefit with the requested agent (e.g., stabilization, decreased disease progression) (medical records required) **AND**
3. If the requested agent is Tyvaso for a diagnosis of pulmonary hypertension associated with interstitial lung disease (PH-ILD, WHO group 3), then the patient will continue standard of care therapy for ILD (e.g., Ofev) **AND**
4. If the request is for ONE of the following brand agents with an available generic equivalent (listed below), then ONE of the following:

Brand	Generic Equivalent
Revatio (tablet, oral suspension)	sildenafil (tablet, oral suspension)
Adcirca	tadalafil
Tracleer 6.25 mg and 125 mg tablets	bosentan 6.25 mg and 125 mg tablets
Letaris	ambrisentan

   A. The patient's medication history includes the required generic equivalent as indicated by:
      1. Evidence of a paid claim(s) **OR**
      2. The prescriber has stated that the patient has tried the generic equivalent AND the generic equivalent was discontinued due to lack of effectiveness or an adverse event **OR**
   B. The patient has an intolerance or hypersensitivity to the generic equivalent that is not expected to occur with the brand agent **OR**
   C. The patient has an FDA labeled contraindication to the generic equivalent that is not expected to occur with the brand agent **OR**
   D. The prescriber has provided information to support the use of the requested brand agent over the generic equivalent **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 the generic equivalent cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**
5. If the request is for Tadliq, then ONE of the following:
   A. The patient's medication history includes generic tadalafil tablets as indicated by:
      1. Evidence of a paid claim(s) **OR**
      2. The prescriber has stated that the patient has tried generic tadalafil tablets AND generic tadalafil tablets were discontinued due to lack of effectiveness or an adverse event **OR**
   B. The patient has an intolerance or hypersensitivity to generic tadalafil tablets that is not expected to occur with the requested agent **OR**
   C. The patient has an FDA labeled contraindication to generic tadalafil tablets that is not expected to occur with the requested agent **OR**
   D. The prescriber has provided information to support the use of the requested agent over generic tadalafil tablets **OR**

Module	Clinical Criteria for Approval
	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 generic tadalafil tablets cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 6. If the request is for Liqrev, then ONE of the following: A. The patient's medication history includes generic sildenafil oral suspension as indicated by: 1. Evidence of a paid claim(s) **OR** 2. The prescriber has stated that the patient has tried generic sildenafil oral suspension AND generic sildenafil oral suspension was discontinued due to lack of effectiveness or an adverse event **OR** B. The patient has an intolerance or hypersensitivity to generic sildenafil oral suspension that is not expected to occur with the requested agent **OR** C. The patient has an FDA labeled contraindication to generic sildenafil oral suspension that is not expected to occur with the requested agent **OR** D. The prescriber has provided information to support the use of the requested agent over generic sildenafil oral suspension **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 generic sildenafil oral suspension 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 prescriber is a specialist in the area of the patient's diagnosis (e.g., cardiologist, pulmonologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 8. 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. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND**

Module	Clinical Criteria for Approval
	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. The prescriber has provided information in support of therapy with a higher dose for the requested indication **Length of Approval**: 12 months

• Program Summary: Procysbi (cysteamine bitartrate)

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

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Final Module	Target Agent GPI	Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Targeted NDCs When Exclusions Exist	Final Age Limit	Preferred Status	Effective Date
	564000301065	Procysbi	cysteamine bitartrate cap delayed release	25 MG; 75 MG	M; N; O; Y				
	564000301030	Procysbi	cysteamine bitartrate delayed release granules packet	300 MG; 75 MG	M; N; O; Y				

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has an FDA approved 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 **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. ONE of the following: A. The patient has tried and had an inadequate response to Cystagon (immediate release cysteamine) **OR** B. The patient has an intolerance or hypersensitivity to Cystagon that is not expected to occur with the requested agent **OR** C. The patient has an FDA labeled contraindication to Cystagon that is not expected to occur with the requested agent **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**

Module	Clinical Criteria for Approval
	E. The prescriber has provided documentation that Cystagon cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 4. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months

• Program Summary: Rayos

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

TARGET AGENTS

Rayos (prednisone delayed release tablet)

Brand (generic)	GPI	Multisource Code
Rayos (prednisone delayed release tablet)		
1 mg oral tablet	22100045000610	M, N, O, or Y
2 mg oral tablet	22100045000620	M, N, O, or Y
5 mg oral tablet	22100045000630	M, N, O, or Y

PRIOR AUTHORIZATION THERAPY CRITERIA FOR APPROVAL

Evaluation

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

1. The patient has an 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. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication
   AND
3. ONE of the following:
   A. The patient has tried and had an inadequate response to BOTH a generic oral prednisone AND at least 1 other different generic oral corticosteroid (e.g., dexamethasone, methylprednisolone, prednisolone)
      OR
   B. The patient has an intolerance or hypersensitivity to BOTH a generic oral prednisone AND at least 1 other different generic oral corticosteroid that would NOT be expected to occur with the requested agent
      OR
   C. The patient has an FDA labeled contraindication to ALL generic oral corticosteroids that would NOT be expected to occur with the requested agent
      OR
   D. The patient is currently being treated with the requested agent as indicated by ALL of the following:
      i. A statement by the prescriber that the patient is currently taking the requested agent
         AND
      ii. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent
         AND
      iii. 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 generic oral 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

AND

4. The patient does NOT have any FDA labeled contraindications to the requested agent

Length of Approval: 6 months

• Program Summary: Self-Administered Oncology Agents

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
21406010200310		Abiraterone Acetate Tab 125 MG		120	Tablets	30	DAYS					
2156006000B730		Selinexor Tab Therapy Pack 20 MG (100 MG Once Weekly)		20	Tablets	28	DAYS					
2156006000B712		Selinexor Tab Therapy Pack 20 MG (40 MG Once Weekly)		8	Tablets	28	DAYS					
2156006000B715		Selinexor Tab Therapy Pack 20 MG (40 MG Twice Weekly)		16	Tablets	28	DAYS					
2156006000B750		Selinexor Tab Therapy Pack 20 MG (60 MG Once Weekly)		12	Tablets	28	DAYS					
2156006000B740		Selinexor Tab Therapy Pack 20 MG (80 MG Once Weekly)		16	Tablets	28	DAYS					
215325300003	Afinitor	everolimus tab	10 MG; 2.5 MG; 5 MG; 7.5 MG	30	Tablets	30	DAYS					
21532530007310	Afinitor disperz	Everolimus Tab for Oral Susp 2 MG	2 MG	60	Tablets	30	DAYS	Calculation is based on 4.5 mg/m^2 with a standard BSA of 2.0 and rounding up to nearest full dose				
21532530007320	Afinitor disperz	Everolimus Tab for Oral Susp 3 MG	3 MG	90	Tablets	30	DAYS					
21532530007340	Afinitor disperz	Everolimus Tab for Oral Susp 5 MG	5 MG	60	Tablets	30	DAYS					
215305071001	Alecensa	alectinib hcl cap	150 MG	240	Capsules	30	DAYS					

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
21530510000330	Alunbrig	Brigatinib Tab	30 MG	120	Tablets	30	DAYS					
21530510000350	Alunbrig	Brigatinib Tab	90 MG	30	Tablets	30	DAYS					
21530510000365	Alunbrig	Brigatinib Tab	180 MG	30	Tablets	30	DAYS					
2153051000B720	Alunbrig	Brigatinib Tab Initiation Therapy Pack	90 & 180 MG	30	Tablets	180	DAYS					
214900090003	Ayvakit	avapritinib tab	100 MG; 200 MG; 25 MG; 300 MG; 50 MG	30	Tablets	30	DAYS					
21532225000325	Balversa	erdafitinib tab	4 MG	60	Tablets	30	DAYS					
21532225000320	Balversa	Erdafitinib Tab 3 MG	3 MG	90	Tablets	30	DAYS					
21532225000330	Balversa	Erdafitinib Tab 5 MG	5 MG	30	Tablets	30	DAYS					
2170007750E520	Besremi	Ropeginterferon alfa-	500 MCG/ML	2	Syringes	28	DAYS					
21531812000320	Bosulif	Bosutinib Tab	100 MG	90	Tablets	30	DAYS					
215318120003	Bosulif	bosutinib tab	400 MG; 500 MG	30	Tablets	30	DAYS					
215320400001	Braftovi	encorafenib cap	75 MG	180	Capsules	30	DAYS					
21532195000120	Brukinsa	zanubrutinib cap	80 MG	120	Capsules	30	DAYS					
21533010100320	Cabometyx	Cabozantinib S-Malate Tab	20 MG	30	Tablets	30	DAYS					
21533010100330	Cabometyx	Cabozantinib S-Malate Tab	40 MG	30	Tablets	30	DAYS					
21533010100340	Cabometyx	Cabozantinib S-Malate Tab	60 MG	30	Tablets	30	DAYS					
215321030001	Calquence	acalabrutinib cap	100 MG	60	Capsules	30	DAYS					
215321035003	Calquence	acalabrutinib maleate tab	100 MG	60	Tablets	30	DAYS					
21533085000320	Caprelsa	Vandetanib Tab	100 MG	60	Tablets	30	DAYS					
21533085000340	Caprelsa	Vandetanib Tab	300 MG	30	Tablets	30	DAYS					
21533010106470	Cometriq	Cabozantinib S-Mal Cap	80 & 20 MG	1	Carton	28	DAYS					
21533010106480	Cometriq	Cabozantinib S-Mal Cap	3 x 20 MG & 80 MG	1	Carton	28	DAYS					
21533010106460	Cometriq	Cabozantinib S-Malate Cap	20 MG	1	Carton	28	DAYS					
215380300001	Copiktra	duvelisib cap	15 MG; 25 MG	56	Capsules	28	DAYS					
215335302003	Cotellic	cobimetinib fumarate tab	20 MG	63	Tablets	28	DAYS					
21370030300335	Daurismo	Glasdegib Maleate Tab 100 MG (Base Equivalent)	100 MG	30	Tablets	30	DAYS					
21370030300320	Daurismo	Glasdegib Maleate Tab 25 MG (Base Equivalent)	25 MG	60	Tablets	30	DAYS					

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
21370070000120	Erivedge	Vismodegib Cap 150 MG	150 MG	30	Capsules	30	DAYS					
21402410000360	Erleada	apalutamide tab	240 MG	30	Tablets	30	DAYS					
21402410000320	Erleada	Apalutamide Tab 60 MG	60 MG	120	Tablets	30	DAYS					
21360050600120	Exkivity	Mobocertinib Succinate Cap	40 MG	120	Capsules	30	DAYS					
215315501001	Farydak	panobinostat lactate cap	10 MG; 15 MG; 20 MG	6	Capsules	21	DAYS					
21533076250120	Fotivda	Tivozanib HCl Cap	0.89 MG	21	Capsules	28	DAYS					
21533076250130	Fotivda	Tivozanib HCl Cap	1.34 MG	21	Capsules	28	DAYS					
215357500001	Gavreto	pralsetinib cap	100 MG	120	Capsules	30	DAYS					
213600061003	Gilotrif	afatinib dimaleate tab	20 MG; 30 MG; 40 MG	30	Tablets	30	DAYS					
21531835100320	Gleevec	Imatinib Mesylate Tab	100 MG	90	Tablets	30	DAYS					
21531835100340	Gleevec	Imatinib Mesylate Tab	400 MG	60	Tablets	30	DAYS					
2153106000	Ibrance	palbociclib cap; palbociclib tab	100 MG; 125 MG; 75 MG	21	Capsules Tablets	28	DAYS					
21531875100315	Iclusig	Ponatinib HCl Tab	10 MG	30	Tablets	30	DAYS					
21531875100320	Iclusig	Ponatinib HCl Tab	15 MG	30	Tablets	30	DAYS					
21531875100330	Iclusig	Ponatinib HCl Tab	30 MG	30	Tablets	30	DAYS					
21531875100340	Iclusig	Ponatinib HCl Tab	45 MG	30	Tablets	30	DAYS					
21535030200340	Idhifa	Enasidenib Mesylate Tab 100 MG (Base Equivalent)	100 MG	30	Tablets	30	DAYS					
21535030200320	Idhifa	Enasidenib Mesylate Tab 50 MG (Base Equivalent)	50 MG	30	Tablets	30	DAYS					
21532133000110	Imbruvica	Ibrutinib Cap	70 MG	30	Capsules	30	DAYS					
21532133000120	Imbruvica	ibrutinib cap	140 MG	90	Capsules	30	DAYS					
21532133001820	Imbruvica	Ibrutinib Oral Susp	70 MG/ML	216	mL	30	DAYS					
215321330003	Imbruvica	ibrutinib tab	140 MG; 280 MG; 420 MG; 560 MG	30	Tablets	30	DAYS					
21335013000320	Inlyta	Axitinib Tab	1 MG	180	Tablets	30	DAYS					
21335013000340	Inlyta	Axitinib Tab	5 MG	120	Tablets	30	DAYS					
219900022503	Inqovi	decitabine-cedazuridine tab	35-100 MG	5	Tablets	28	DAYS					
21537520200120	Inrebic	Fedratinib HCl Cap 100 MG	100 MG	120	Capsules	30	DAYS					

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
213600300003	Iressa	gefitinib tab	250 MG	30	Tablets	30	DAYS					
215375602003	Jakafi	ruxolitinib phosphate tab	10 MG; 15 MG; 20 MG; 25 MG; 5 MG	60	Tablets	30	DAYS					
21532165000320	Jaypirca	pirtobrutinib tab	50 MG	30	Tablets	30	DAYS					
21532165000330	Jaypirca	pirtobrutinib tab	100 MG	60	Tablets	30	DAYS					
2153107050B720	Kisqali	Ribociclib Succinate Tab Pack 200 MG Daily Dose	200 MG	21	Tablets	28	DAYS					
2153107050B740	Kisqali	Ribociclib Succinate Tab Pack 400 MG Daily Dose (200 MG Tab)	200 MG	42	Tablets	28	DAYS					
2153107050B760	Kisqali	Ribociclib Succinate Tab Pack 600 MG Daily Dose (200 MG Tab)	200 MG	63	Tablets	28	DAYS					
2199000260B730	Kisqali femara 200 dose	Ribociclib 200 MG Dose (200 MG Tab) & Letrozole 2.5 MG TBPK	200 & 2.5 MG	49	Tablets	28	DAYS					
2199000260B740	Kisqali femara 400 dose	Ribociclib 400 MG Dose (200 MG Tab) & Letrozole 2.5 MG TBPK	200 & 2.5 MG	70	Tablets	28	DAYS					
2199000260B760	Kisqali femara 600 dose	Ribociclib 600 MG Dose (200 MG Tab) & Letrozole 2.5 MG TBPK	200 & 2.5 MG	91	Tablets	28	DAYS					
21533565500110	Koselugo	Selumetinib Sulfate Cap 10 MG	10 MG	240	Capsules	30	DAYS					
21533565500125	Koselugo	Selumetinib Sulfate Cap 25 MG	25 MG	120	Capsules	30	DAYS					
21532410000320	Krazati	Adagrasib Tab	200 MG	180	Tablets	30	DAYS					
2133505420B220	Lenvima 10 mg daily dose	Lenvatinib Cap Therapy Pack	10 MG	30	Capsules	30	DAYS					
2133505420B223	Lenvima 12mg daily dose	Lenvatinib Cap Therapy Pack	4 MG	90	Capsules	30	DAYS					
2133505420B240	Lenvima 14 mg daily dose	Lenvatinib Cap Therapy Pack	10 & 4 MG	60	Capsules	30	DAYS					
2133505420B244	Lenvima 18 mg daily dose	Lenvatinib Cap Ther Pack	10 MG & 2 x 4 MG	90	Capsules	30	DAYS					
2133505420B230	Lenvima 20 mg daily dose	Lenvatinib Cap Therapy Pack	10 MG	60	Capsules	30	DAYS					
2133505420B250	Lenvima 24 mg daily dose	Lenvatinib Cap Ther Pack	2 x 10 MG & 4 MG	90	Capsules	30	DAYS					
2133505420B210	Lenvima 4 mg daily dose	Lenvatinib Cap Therapy Pack	4 MG	30	Capsules	30	DAYS					

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
2133505420B215	Lenvima 8 mg daily dose	Lenvatinib Cap Therapy Pack	4 MG	60	Capsules	30	DAYS					
21990002750320	Lonsurf	Trifluridine-Tipiracil Tab 15-6.14 MG	15-6.14 MG	60	Tablets	28	DAYS					
21990002750330	Lonsurf	Trifluridine-Tipiracil Tab 20-8.19 MG	20-8.19 MG	80	Tablets	28	DAYS					
21530556000320	Lorbrena	Lorlatinib Tab	25 MG	90	Tablets	30	DAYS					
21530556000330	Lorbrena	Lorlatinib Tab	100 MG	30	Tablets	30	DAYS					
21532480000320	Lumakras	Sotorasib Tab	120 MG	240	Tablets	30	DAYS					
21532480000340	Lumakras	Sotorasib Tab	320 MG	90	Tablets	30	DAYS					
215355600003	Lynparza	olaparib tab	100 MG; 150 MG	120	Tablets	30	DAYS					
2153222800B720	Lytgobi	Futibatinib Tab Therapy Pack (12 mg daily dose)	4 MG	84	Tablets	28	DAYS					
2153222800B725	Lytgobi	Futibatinib Tab Therapy Pack (16 mg daily dose)	4 MG	112	Tablets	28	DAYS					
2153222800B730	Lytgobi	Futibatinib Tab Therapy Pack (20 mg daily dose)	4 MG	140	Tablets	28	DAYS					
21533570102120	Mekinist	trametinib dimethyl sulfoxide for soln	0.05 MG/ML	1170	mLs	28	DAYS					
21533570100310	Mekinist	Trametinib Dimethyl Sulfoxide Tab 0.5 MG (Base Equivalent)	0.5 MG	90	Tablets	30	DAYS					
21533570100330	Mekinist	Trametinib Dimethyl Sulfoxide Tab 2 MG (Base Equivalent)	2 MG	30	Tablets	30	DAYS					
215335200003	Mektovi	binimetinib tab	15 MG	180	Tablets	30	DAYS					
21533035100320	Nerlynx	Neratinib Maleate Tab	40 MG	180	Tablets	30	DAYS					
21533060400320	Nexavar	Sorafenib Tosylate Tab 200 MG (Base Equivalent)	200 MG	120	Tablets	30	DAYS					
215360451001	Ninlaro	ixazomib citrate cap	2.3 MG; 3 MG; 4 MG	3	Capsules	28	DAYS					
21402425000320	Nubeqa	Darolutamide Tab 300 MG	300 MG	120	Tablets	30	DAYS					
213700602001	Odomzo	sonidegib phosphate cap	200 MG	30	Capsules	30	DAYS					
213000030003	Onureg	azacitidine tab	200 MG; 300 MG	14	Tablets	28	DAYS					
214055700003	Orgovyx	relugolix tab	120 MG	30	Tablets	30	DAYS					

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
21403720100320	Orserdu	elacestrant hydrochloride tab	86 MG	90	Tablets	30	DAYS					
21403720100340	Orserdu	elacestrant hydrochloride tab	345 MG	30	Tablets	30	DAYS					
21532260000340	Pemazyre	Pemigatinib Tab 13.5 MG	13.5 MG	14	Tablets	21	DAYS					
21532260000320	Pemazyre	Pemigatinib Tab 4.5 MG	4.5 MG	14	Tablets	21	DAYS					
21532260000330	Pemazyre	Pemigatinib Tab 9 MG	9 MG	14	Tablets	21	DAYS					
2153801000B720	Piqray 200mg daily dose	Alpelisib Tab Therapy Pack 200 MG Daily Dose	200 MG	28	Tablets	28	DAYS					
2153801000B725	Piqray 250mg daily dose	Alpelisib Tab Pack 250 MG Daily Dose (200 MG & 50 MG Tabs)	200 & 50 MG	56	Tablets	28	DAYS					
2153801000B730	Piqray 300mg daily dose	Alpelisib Tab Pack 300 MG Daily Dose (2x150 MG Tab)	150 MG	56	Tablets	28	DAYS					
214500800001	Pomalyst	pomalidomide cap	1 MG; 2 MG; 3 MG; 4 MG	21	Capsules	28	DAYS	The quantity limits for Pomalyst are based on dosing for multiple myeloma, which is given daily for 21 days of a 28 day cycle				
21533053000320	Qinlock	Ripretinib Tab	50 MG	90	Tablets	30	DAYS					
21535779000120	Retevmo	Selpercatinib Cap	40 MG	180	Capsules	30	DAYS					
21535779000140	Retevmo	Selpercatinib Cap	80 MG	120	Capsules	30	DAYS					
99394050000130	Revlimid	Lenalidomide Cap 10 MG	10 MG	30	Capsules	30	DAYS					
99394050000140	Revlimid	Lenalidomide Cap 15 MG	15 MG	21	Capsules	28	DAYS	The quantity limits for Revlimid 15 mg & 25 mg capsules are based on dosing for multiple myeloma, which is 25 mg daily for				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
								21 days of a 28 day cycle				
99394050000145	Revlimid	Lenalidomide Cap 20 MG	20 MG	21	Capsules	28	DAYS					
99394050000150	Revlimid	Lenalidomide Cap 25 MG	25 MG	21	Capsules	28	DAYS	The quantity limits for Revlimid 15 mg & 25 mg capsules are based on dosing for multiple myeloma, which is 25 mg daily for 21 days of a 28 day cycle				
99394050000120	Revlimid	Lenalidomide Cap 5 MG	5 MG	30	Capsules	30	DAYS					
99394050000110	Revlimid	Lenalidomide Caps 2.5 MG	2.5 MG	30	Capsules	30	DAYS					
21534960000120	Rezlidhia	Olutasidenib Cap	150 MG	60	Capsules	30	DAYS					
21533820000120	Rozlytrek	Entrectinib Cap 100 MG	100 MG	30	Capsules	30	DAYS					
21533820000130	Rozlytrek	Entrectinib Cap 200 MG	200 MG	90	Capsules	30	DAYS					
21535570200320	Rubraca	Rucaparib Camsylate Tab 200 MG (Base Equivalent)	200 MG	120	Tablets	30	DAYS					
21535570200325	Rubraca	Rucaparib Camsylate Tab 250 MG (Base Equivalent)	250 MG	120	Tablets	30	DAYS					
21535570200330	Rubraca	Rucaparib Camsylate Tab 300 MG (Base Equivalent)	300 MG	120	Tablets	30	DAYS					
21533030000130	Rydapt	Midostaurin Cap 25 MG	25 MG	240	Capsules	30	DAYS					
21531806100320	Scemblix	Asciminib HCl Tab	20 MG	60	Tablets	30	DAYS					
21531806100340	Scemblix	Asciminib HCl Tab	40 MG	300	Tablets	30	DAYS					
21531820000320	Sprycel	Dasatinib Tab	20 MG	90	Tablets	30	DAYS					
21531820000340	Sprycel	Dasatinib Tab	50 MG	30	Tablets	30	DAYS					
21531820000350	Sprycel	Dasatinib Tab	70 MG	30	Tablets	30	DAYS					
21531820000354	Sprycel	Dasatinib Tab	80 MG	30	Tablets	30	DAYS					
21531820000360	Sprycel	Dasatinib Tab	100 MG	30	Tablets	30	DAYS					
21531820000380	Sprycel	Dasatinib Tab	140 MG	30	Tablets	30	DAYS					

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
2153305000	Stivarga	regorafenib tab	40 MG	84	Tablets	28	DAYS	based 160 mg daily for 21 days of a 28 day cycle				
21533070300120	Sutent	Sunitinib Malate Cap 12.5 MG (Base Equivalent)	12.5 MG	90	Capsules	30	DAYS					
21533070300130	Sutent	Sunitinib Malate Cap 25 MG (Base Equivalent)	25 MG	30	Capsules	30	DAYS					
21533070300135	Sutent	Sunitinib Malate Cap 37.5 MG (Base Equivalent)	37.5 MG	30	Capsules	30	DAYS					
21533070300140	Sutent	Sunitinib Malate Cap 50 MG (Base Equivalent)	50 MG	30	Capsules	30	DAYS					
215337162003	Tabrecta	capmatinib hcl tab	150 MG; 200 MG	120	Tablets	30	DAYS					
215320251001	Tafinlar	dabrafenib mesylate cap	50 MG; 75 MG	120	Capsules	30	DAYS					
21532025107320	Tafinlar	dabrafenib mesylate tab for oral susp	10 MG	840	Tablets	28	DAYS					
213600682003	Tagrisso	osimertinib mesylate tab	40 MG; 80 MG	30	Tablets	30	DAYS					
21535580400105	Talzenna	talazoparib tosylate cap	0.1 MG	30	Capsules	30	DAYS					
21535580400112	Talzenna	talazoparib tosylate cap	0.35 MG	30	Capsules	30	DAYS					
21535580400114	Talzenna	Talazoparib Tosylate Cap	0.5 MG	30	Capsules	30	DAYS					
21535580400118	Talzenna	Talazoparib Tosylate Cap	0.75 MG	30	Capsules	30	DAYS					
21535580400110	Talzenna	Talazoparib Tosylate Cap 0.25 MG (Base Equivalent)	0.25 MG	90	Capsules	30	DAYS					
21535580400120	Talzenna	Talazoparib Tosylate Cap 1 MG (Base Equivalent)	1 MG	30	Capsules	30	DAYS					
21360025100320	Tarceva	Erlotinib HCl Tab	25 MG	60	Tablets	30	DAYS					
21360025100330	Tarceva	Erlotinib HCl Tab	100 MG	30	Tablets	30	DAYS					
21360025100360	Tarceva	Erlotinib HCl Tab	150 MG	30	Tablets	30	DAYS					
215318602001	Tasigna	nilotinib hcl cap	150 MG; 200 MG; 50 MG	120	Capsules	30	DAYS					
215336752003	Tazverik	tazemetostat hbr tab	200 MG	240	Tablets	30	DAYS					
21533773100320	Tepmetko	Tepotinib HCl Tab	225 MG	60	Tablets	30	DAYS					

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
99392070000130	Thalomid	Thalidomide Cap 100 MG	100 MG	30	Tablets	30	DAYS					
99392070000135	Thalomid	Thalidomide Cap 150 MG	150 MG	60	Capsules	30	DAYS					
99392070000140	Thalomid	Thalidomide Cap 200 MG	200 MG	60	Capsules	30	DAYS					
99392070000120	Thalomid	Thalidomide Cap 50 MG	50 MG	30	Capsules	30	DAYS					
21534940000320	Tibsovo	Ivosidenib Tab 250 MG	250 MG	60	Tablets	30	DAYS					
2153223540B235	Truseltiq	Infigratinib Phos Cap Pack (125 mg daily dose)	100 & 25 MG	42	Capsules	28	DAYS					
2153223540B220	Truseltiq	infigratinib phos cap ther pack (50 mg daily dose)	25 MG	42	Capsules	28	DAYS					
2153223540B225	Truseltiq	Infigratinib Phos Cap Ther Pack (75 mg daily dose)	25 MG	63	Capsules	28	DAYS					
2153223540B230	Truseltiq	Infigratinib Phos Cap Ther Pack (100 mg daily dose)	100 MG	21	Capsules	28	DAYS					
21170080000320	Tukysa	Tucatinib Tab	50 MG	300	Tablets	30	DAYS					
21170080000340	Tukysa	Tucatinib Tab	150 MG	120	Tablets	30	DAYS					
21533045010110	Turalio	Pexidartinib HCl Cap	125 MG	120	Capsules	30	DAYS					
21533045010120	Turalio	Pexidartinib HCl Cap	200 MG	120	Capsules	30	DAYS					
21533026100320	Tykerb	Lapatinib Ditosylate Tab	250 MG	180	Tablets	30	DAYS					
21470080000320	Venclexta	Venetoclax Tab 10 MG	10 MG	60	Tablets	30	DAYS					
21470080000360	Venclexta	Venetoclax Tab 100 MG	100 MG	180	Tablets	30	DAYS					
21470080000340	Venclexta	Venetoclax Tab 50 MG	50 MG	30	Tablets	30	DAYS					
2147008000B720	Venclexta starting pack	Venetoclax Tab Therapy Starter Pack 10 & 50 & 100 MG	10 & 50 & 100 MG	1	Pack	180	DAYS					
215310100003	Verzenio	abemaciclib tab	100 MG; 150 MG; 200 MG; 50 MG	60	Tablets	30	DAYS					
21533835200150	Vitrakvi	Larotrectinib Sulfate Cap 100 MG (Base Equivalent)	100 MG	60	Capsules	30	DAYS					
21533835200120	Vitrakvi	Larotrectinib Sulfate Cap 25 MG (Base Equivalent)	25 MG	180	Capsules	30	DAYS					
21533835202020	Vitrakvi	Larotrectinib Sulfate Oral Soln 20 MG/ML (Base Equivalent)	20 MG/ML	300	mLs	30	DAYS					

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
213600190003	Vizimpro	dacomitinib tab	15 MG; 30 MG; 45 MG	30	Tablets	30	DAYS					
215375501001	Vonjo	pacritinib citrate cap	100 MG	120	Capsules	30	DAYS					
21533042100320	Votrient	Pazopanib HCl Tab	200 MG	120	Tablets	30	DAYS					
21421020000320	Welireg	Belzutifan Tab	40 MG	90	Tablets	30	DAYS					
215305170001	Xalkori	crizotinib cap	200 MG; 250 MG	120	Capsules	30	DAYS					
21533020200320	Xospata	Gilteritinib Fumarate Tablet	40 MG	90	Tablets	30	DAYS					
2156006000B760	Xpovio	Selinexor Tab Therapy Pack (40 mg once weekly)	40 MG	4	Tablets	28	DAYS					
2156006000B765	Xpovio	Selinexor Tab Therapy Pack (40 mg twice weekly)	40 MG	8	Tablets	28	DAYS					
2156006000B770	Xpovio	Selinexor Tab Therapy Pack (80 mg once weekly)	40 MG	8	Tablets	28	DAYS					
2156006000B775	Xpovio	Selinexor Tab Therapy Pack (100 mg once weekly)	50 MG	8	Tablets	28	DAYS					
2156006000B780	Xpovio	Selinexor Tab Therapy Pack (60 mg once weekly)	60 MG	4	Tablets	28	DAYS					
2156006000B755	Xpovio 60 mg twice weekly	Selinexor Tab Therapy Pack 20 MG (60 MG Twice Weekly)	20 MG	24	Tablets	28	DAYS					
2156006000B720	Xpovio 80 mg twice weekly	Selinexor Tab Therapy Pack 20 MG (80 MG Twice Weekly)	20 MG	32	Tablets	28	DAYS					
214024300001	Xtandi	enzalutamide cap	40 MG	120	Capsules	30	DAYS					
21402430000320	Xtandi	Enzalutamide Tab	40 MG	120	Tablets	30	DAYS					
21402430000340	Xtandi	Enzalutamide Tab	80 MG	60	Tablets	30	DAYS					
21406010250310	Yonsa	Abiraterone acetate tab	125 MG	120	Tablets	30	DAYS					
215355502001	Zejula	niraparib tosylate cap	100 MG	90	Capsules	30	DAYS					
215355502003	Zejula	niraparib tosylate tab	100 MG; 200 MG; 300 MG	30	Tablets	30	DAYS					
21532080000320	Zelboraf	Vemurafenib Tab ; vemurafenib tab	240 MG	240	Tablets	30	DAYS					
21531575000120	Zolinza	Vorinostat Cap 100 MG	100 MG	120	Capsules	30	DAYS					
215380400003	Zydelig	idelalisib tab	100 MG; 150 MG	60	Tablets	30	DAYS					

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
215305140003	Zykadia	ceritinib tab	150 MG	90	Tablets	30	DAYS					
21406010200320	Zytiga	Abiraterone Acetate Tab 250 MG	250 MG	120	Tablets	30	DAYS					
21406010200330	Zytiga	Abiraterone Acetate Tab 500 MG	500 MG	60	Tablets	30	DAYS					

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
PA QL	**Initial Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. Information has been provided that indicates the patient is currently being treated with the requested agent within the past 180 days **OR** B. The prescriber states the patient is being treated with the requested agent within the past 180 days AND is at risk if therapy is changed **OR** C. ALL of the following: 1. ONE of the following: A. The patient has an FDA approved indication for the requested agent **OR** B. The patient has an indication that is supported by compendia (NCCN Compendium level of evidence 1 or 2A, or 2B, DrugDex 1, 2A, or 2B, AHFS, Wolters Kluwer Lexi-Drugs level of evidence A, Clinical Pharmacology) [i.e., this indication must be supported by ALL requirements in the compendia (e.g., performance status, disease severity, previous failures, monotherapy vs combination therapy, etc.)] for the requested agent **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. ONE of the following: A. The requested indication does NOT require specific genetic/diagnostic testing per FDA labeling or compendia (NCCN Compendium level of evidence 1 or 2A, or 2B, DrugDex 1, 2A, or 2B, AHFS, Wolters Kluwer Lexi-Drugs level of evidence A, Clinical Pharmacology) for the requested agent **OR** B. The requested indication requires genetic/specific diagnostic testing per FDA labeling or compendia (NCCN Compendium level of evidence 1 or 2A, or 2B, DrugDex 1, 2A, or 2B, AHFS, Wolters Kluwer Lexi-Drugs level of evidence A, Clinical Pharmacology) for the requested agent AND BOTH of the following: 1. Genetic/specific diagnostic testing has been completed **AND** 2. The results of the genetic/specific diagnostic testing indicate therapy with the requested agent is appropriate **AND** 4. ONE of the following: A. The requested agent is being used as monotherapy AND is approved for use as monotherapy in the FDA labeling or supported by compendia (NCCN Compendium level of evidence 1 or 2A, or 2B, DrugDex 1, 2A, or 2B, AHFS, Wolters Kluwer Lexi-Drugs level of evidence A, Clinical Pharmacology) for the requested indication **OR**

Module	Clinical Criteria for Approval
	B. The requested agent will be used as combination therapy with all agent(s) and/or treatments (e.g., radiation) listed for concomitant use in the FDA labeling or compendia (NCCN Compendium level of evidence 1 or 2A, or 2B, DrugDex 1, 2A, or 2B, AHFS, Wolters Kluwer Lexi-Drugs level of evidence A, Clinical Pharmacology) for the requested indication **AND** 5. ONE of the following: A. The requested agent will be used as a first-line agent AND is FDA labeled or supported by compendia (NCCN Compendium level of evidence 1 or 2A, or 2B, DrugDex 1, 2A, or 2B, AHFS, Wolters Kluwer Lexi-Drugs level of evidence A, Clinical Pharmacology) as a first-line agent for the requested indication **OR** B. The patient has tried and had an inadequate response to the appropriate number and type(s) of prerequisite agent(s) listed in FDA labeling or compendia (NCCN Compendium level of evidence 1 or 2A, or 2B, DrugDex 1, 2A, or 2B, AHFS, Wolters Kluwer Lexi-Drugs level of evidence A, Clinical Pharmacology) for the requested indication **OR** C. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to the appropriate number and type(s) of prerequisite agent(s) listed in the FDA labeling or compendia (NCCN Compendium level of evidence 1 or 2A, or 2B, DrugDex 1, 2A, or 2B, AHFS, Wolters Kluwer Lexi-Drugs level of evidence A, Clinical Pharmacology) for the requested indication **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 the appropriate prerequisite agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 2. The patient does not have any FDA labeled contraindications to the requested agent **AND** 3. The patient does not have any FDA labeled limitation(s) of use that is otherwise not supported in NCCN to the requested agent **Length of Approval:** Up to 3 months for dose titration requests and Vitrakvi; Up to 12 months for all other requests, approve starter packs and loading doses where appropriate and maintenance dose for the remainder of the authorization 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 **AND** 2. ONE of the following: A. The requested agent is Vitrakvi AND the patient has experienced clinical benefit (i.e., partial response, complete response, or stable disease) with the requested agent **OR** B. The requested agent is NOT Vitrakvi **AND**

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	3. The patient does not have any FDA labeled contraindications to the requested agent **AND** 4. The patient does not have any FDA labeled limitation(s) of use that is otherwise not supported in NCCN to the requested agent **Length of Approval:** Up to 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. FDA Companion Diagnostics: https://www.fda.gov/medical-devices/vitro-diagnostics/list-cleared-or-approved-companion-diagnostic-devices-vitro-and-imaging-tools

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

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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. The prescriber has provided information in support of therapy with a higher dose for the requested indication **Length of Approval**: Up to 3 months for dose titration requests over the program quantity limit and Vitrakvi; Up to 12 months for all other requests, approve starter packs/loading doses where appropriate and maintenance doses for the remainder of the authorization

• Program Summary: Weight Loss Agents

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

POLICY AGENT SUMMARY QUANTITY LIMIT

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
61200010100305		Benzphetamine HCl Tab 25 MG		90	Tablets	30	DAYS					
61200010100310		Benzphetamine HCl Tab 50 MG	50 MG	90	Tablets	30	DAYS					
61200020100305		Diethylpropion HCl Tab 25 MG	25 MG	90	Tablet	30	DAYS					
61200020107510		Diethylpropion	75 MG	30	Tablets	30	DAYS					

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
		HCl Tab ER 24HR 75 MG										
61200050107010		Phendimetrazine Tartrate Cap ER 24HR 105 MG	105 MG	30	Capsules	30	DAYS					
61200050100305		Phendimetrazine Tartrate Tab 35 MG	35 MG	180	Tablets	30	DAYS					
61200070100110		Phentermine HCl Cap 15 MG	15 MG	30	Capsules	30	DAYS					
61200070100115		Phentermine HCl Cap 30 MG	30 MG	30	Capsules	30	DAYS					
61200070100120	Adipex-p	Phentermine HCl Cap 37.5 MG	37.5 MG	30	Capsules	30	DAYS					
61200070100310	Adipex-p	Phentermine HCl Tab 37.5 MG	37.5 MG	30	Tablets	30	DAYS					
61259902507420	Contrave	Naltrexone HCl-Bupropion HCl Tab ER 12HR 8-90 MG	8-90 MG	120	Tablets	30	DAYS					
61200070100305	Lomaira	Phentermine HCl Tab 8 MG	8 MG	90	Tablets	30	DAYS					
61209902307040	Qsymia	Phentermine HCl-Topiramate Cap ER 24HR 11.25-69 MG	11.25-69 MG	30	Capsules	30	DAYS					
61209902307050	Qsymia	Phentermine HCl-Topiramate Cap ER 24HR 15-92 MG	15-92 MG	30	Capsules	30	DAYS					
61209902307020	Qsymia	Phentermine HCl-Topiramate Cap ER 24HR 3.75-23 MG	3.75-23 MG	30	Capsules	30	DAYS					
61209902307030	Qsymia	Phentermine HCl-Topiramate Cap ER 24HR 7.5-46 MG	7.5-46 MG	30	Capsules	30	DAYS					
6125205000D220	Saxenda	Liraglutide (Weight Mngmt) Soln Pen-Inj 18 MG/3ML (6 MG/ML)	18 MG/3ML	15	mLs	30	DAYS					
6125207000D520	Wegovy	Semaglutide (Weight Mngmt) Soln Auto-Injector	0.25 MG/0.5 ML	8	Pens	180	DAYS	*This strength is not approvable for mainten				

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
								ance dosing				
6125207000D525	Wegovy	Semaglutide (Weight Mngmt) Soln Auto-Injector	0.5 MG/0.5 ML	8	Pens	180	DAYS	*This strength is not approvable for maintenance dosing				
6125207000D530	Wegovy	Semaglutide (Weight Mngmt) Soln Auto-Injector	1 MG/0.5 ML	8	Pens	180	DAYS	*This strength is not approvable for maintenance dosing				
6125207000D535	Wegovy	Semaglutide (Weight Mngmt) Soln Auto-Injector	1.7 MG/0.75 ML	4	Pens	28	DAYS					
6125207000D540	Wegovy	Semaglutide (Weight Mngmt) Soln Auto-Injector	2.4 MG/0.75 ML	4	Pens	28	DAYS					
61253560000120	Xenical	Orlistat Cap 120 MG	120 MG	90	Capsules	30	DAYS					

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation (Patient new to therapy, new to Prime, or attempting a repeat weight loss course of therapy) **Target Agent(s)** will be approved when ALL the following are met: 1. ONE of the following: A. The patient is 17 years of age or over and ALL of the following: 1. ONE of the following: A. The patient has a diagnosis of obesity, confirmed by a BMI greater than or equal to 30 kg/m^2 OR a BMI greater than or equal to 25 kg/m^2 if the patient is of South Asian, Southeast Asian, or East Asian descent **OR** B. The patient has a BMI greater than or equal to 27 kg/m^2 with at least one weight-related comorbidity/risk factor/complication (e.g., diabetes, dyslipidemia, coronary artery disease) **AND** 2. The patient has been on a weight loss regimen of a low-calorie diet, increased physical activity, and behavioral modifications for a minimum of 6 months prior to initiating therapy with the requested agent **AND** 3. The patient did not achieve a weight loss of 1 pound or more per week while on the

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	weight loss regimen prior to initiating therapy with the requested agent **AND** 4. The patient is currently on and will continue a weight loss regimen of a low-calorie diet, increased physical activity, and behavioral modifications **OR** B. The patient is 12 to 16 years of age and ALL of the following: 1. ONE of the following: A. The patient has a diagnosis of obesity, confirmed by a BMI greater than or equal to 95th percentile for age and gender **OR** B. The patient has a diagnosis of obesity, confirmed by a BMI greater than or equal to 30 kg/m^2 **OR** C. The patient has a BMI greater than or equal to 85th percentile for age and gender AND at least one severe weight-related comorbidity/risk factor/complication **AND** 2. The patient has been on a weight loss regimen of a low-calorie diet, increased physical activity, and behavioral modifications for a minimum of 6 months prior to initiating therapy with the requested agent **AND** 3. The patient did not achieve a weight loss of 1 pound or more per week while on the weight loss regimen prior to initiating therapy with the requested agent **AND** 4. The patient is currently on and will continue a weight loss regimen of a low-calorie diet, increased physical activity, and behavioral modifications **AND** 2. If the patient has an FDA approved indication, ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 4. The patient will NOT be using the requested agent in combination with another targeted weight loss agent for the requested indication **AND** 5. ONE of the following: A. The patient has not tried a targeted weight loss agent in the past 12 months **OR** B. The patient has tried a targeted weight loss agent for a previous course of therapy in the past 12 months AND the prescriber anticipates success with repeating therapy **AND** 6. ONE of the following: A. The requested agent is benzphetamine, diethylpropion, phendimetrazine, or phentermine **OR** B. The requested agent is Qsymia and ONE of the following: 1. The requested dose is 3.75mg/23mg **OR** 2. The patient is currently being treated with Qsymia, the requested dose is greater than 3.75 mg/23 mg AND ONE of the following: A. ONE of the following: 1. For adults, the patient has demonstrated and maintained a weight loss of greater than or equal to 5% from baseline (prior to initiation of the requested agent) **OR** 2. For pediatric patients aged 12 years and older, the patient has experienced a reduction of at least 5% of baseline BMI (prior to initiation of the requested agent) **OR** B. The patient received less than 14 weeks of therapy **OR** C. The patient's dose is being titrated upward **OR** D. The patient has received less than 12 weeks (3 months) of therapy on the 15mg/92mg strength **OR** 3. The prescriber has provided information in support of therapy for the requested dose for this patient **OR** C. The requested agent is Contrave and ONE of the following 1. The patient is newly starting therapy **OR** 2. The patient is currently being treated and has received less than 16 weeks (4 months) of

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	therapy **OR** 3. The patient has achieved and maintained a weight loss of greater than or equal to 5% from baseline (prior to initiation of requested agent) **OR** D. The requested agent is Xenical (orlistat) and ONE of the following: 1. The patient is 12 to 16 years of age and ONE of the following: A. The patient is newly starting therapy **OR** B. The patient is currently being treated and has received less than 12 weeks (3 months) of therapy **OR** C. The patient has achieved and maintained a weight loss of greater than 4% from baseline (prior to initiation of requested agent) **OR** 2. The patient is 17 years of age or over and ONE of the following: A. The patient is newly starting therapy **OR** B. The patient is currently being treated and has received less than 12 weeks (3 months) of therapy **OR** C. The patient has achieved and maintained a weight loss of greater than or equal to 5% from baseline (prior to initiation of requested agent) **OR** E. The requested agent is Saxenda and ALL of the following: 1. The patient will NOT be using the requested agent in combination with another GLP-1 receptor agonist agent **AND** 2. ONE of the following: A. The patient is 18 years of age or over and ONE of the following: 1. The patient is newly starting therapy **OR** 2. The patient is currently being treated and has received less than 16 weeks (4 months) of therapy **OR** 3. The patient has achieved and maintained a weight loss of greater than or equal to 4% from baseline (prior to initiation of requested agent) **OR** B. The patient is pediatric (12 to less than 18 years of age) and BOTH of the following: 1. The requested agent is NOT being used to treat type 2 diabetes **AND** 2. ONE of the following: A. The patient is newly starting therapy **OR** B. The patient is currently being treated and has received less than 20 weeks (5 months) of therapy **OR** C. The patient has achieved and maintained a reduction in BMI of greater than or equal to 1% from baseline (prior to initiation of requested agent) **OR** F. The requested agent is Wegovy and ALL of the following: 1. The patient will NOT be using the requested agent in combination with another GLP-1 receptor agonist agent **AND** 2. The patient does NOT have a history of pancreatitis **AND** 3. ONE of the following: A. The patient is newly starting therapy **OR** B. The patient is currently being treated and has received less than 52 weeks (1 year) of therapy **OR** C. ONE of the following: 1. The patient is an adult AND has achieved and maintained a weight loss of greater than or equal to 5% from baseline (prior to initiation of the requested agent) **OR** 2. The patient is pediatric (12 to less than 18 years of age) AND has achieved and maintained a reduction in BMI of at least 5% from baseline (prior to initiation of the requested agent)

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	Length of Approval: • For Wegovy: 12 months • For Saxenda pediatric patients (age 12 to less than 18): 5 months • For Saxenda (adults) and Contrave: 4 months • For all other agents: 3 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria. **Renewal Evaluation** (Patient continuing a current weight loss course of therapy) **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 **AND** 2. The patient is currently on and will continue to be on a weight loss regimen of a low-calorie diet, increased physical activity, and behavioral modifications **AND** 3. The patient does NOT have any FDA labeled contraindications to the requested agent **AND** 4. For Saxenda only, BOTH of the following: A. The requested agent is NOT being used to treat type 2 diabetes in pediatric patients (12 to less than 18 years of age) **AND** B. The patient will NOT be using the requested agent in combination with another GLP-1 receptor agonist agent **AND** 5. For Wegovy only, ALL of the following: A. The requested dose is 1.7 mg or 2.4 mg **AND** B. The patient will NOT be using the requested agent in combination with another GLP-1 receptor agonist agent **AND** C. The patient does NOT have a history of pancreatitis **AND** 6. The patient meets ONE of the following: A. The patient has achieved and maintained a weight loss greater than or equal to 5% from baseline (prior to initiation of requested agent) **OR** B. For Saxenda only, ONE of the following: 1. If the patient is 18 years of age or over, the patient has achieved and maintained a weight loss greater than or equal to 4% from baseline (prior to initiation of requested agent) **OR** 2. If the patient is pediatric (12 to less than 18 years of age), the patient has achieved and maintained a reduction in BMI of greater than or equal to 1% from baseline (prior to initiation of requested agent) **OR** C. For Qsymia only, ONE of the following: 1. For pediatric patients aged 12 years and older, the patient has achieved and maintained a reduction of at least 5% of baseline (prior to initiation of the requested agent) BMI **OR** 2. The patient has achieved and maintained a weight loss less than 5% from baseline (prior to initiation of requested agent) for adults, or a reduction in BMI less than 5% from baseline (prior to initiation of the requested agent) for pediatric patients aged 12 years or older, AND BOTH of the following: A. The patient's dose is being titrated upward (for the 3.75 mg/23 mg, 7.5 mg/46 mg or 11.25 mg/69 mg strengths only) **AND** B. The patient has received less than 12 weeks of therapy on the 15mg/92mg strength **OR** D. For Xenical (orlistat) only, ONE of the following: 1. The patient 12 to 16 years of age **AND** has achieved and maintained a weight loss greater

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	than 4% from baseline (prior to initiation of requested agent) **OR** 2. The patient is 17 years of age or over **AND** has achieved and maintained a weight loss greater than or equal to 5% from baseline (prior to initiation of requested agent) **OR** E. For Wegovy only, ONE of the following: 1. The patient is 12 years of age and over **AND** has received less than 52 weeks of therapy on the maximum-tolerated dose (1.7 mg or 2.4 mg) **OR** 2. The patient is pediatric (12 to less than 18 years of age) **AND** has achieved and maintained a reduction in BMI of at least 5% from baseline (prior to initiation of the requested agent) **AND** 7. If the patient is 12 to less than 18 years of age, the current BMI is greater than 85th percentile for age and gender **AND** 8. The patient will NOT be using the requested agent in combination with another targeted weight loss agent for the requested indication **Length of Approval:** • Qsymia: greater than or equal to 5% weight loss from baseline (adults); greater than or equal to 5% reduction in BMI from baseline (pediatrics): 12 months • Qsymia less than 5% weight loss from baseline (adults); less than 5% reduction in BMI from baseline (pediatrics): 3 months • All other agents: 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	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. The prescriber has provided information in support of therapy with a higher dose for the requested indication **Length of Approval**: • Initial Approval: ○ For Wegovy: 12 months ○ For Saxenda pediatric patients (age 12 to less than 18): 5 months ○ For Saxenda (adults) and Contrave: 4 months ○ For all other agents: 3 months • Renewal Approval: ○ Qsymia: greater than or equal to 5% weight loss from baseline (adults); greater than or equal to 5% reduction in BMI from baseline (pediatrics): 12 months

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	○ Qsymia. less than 5% weight loss from baseline (adults); less than 5% reduction in BMI from baseline (pediatrics): 3 months ○ All other agents: 12 months