Mass General Brigham
Health Plan

Medical Necessity
Effective 07/01/2026

Plan	☒ MassHealth UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical Benefit** **Pharmacy Benefit**	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Exceptions	N/A		

Overview

The purpose of this policy is to clarify the procedures used for reviewing prior authorization (PA) requests for the following drug therapies:

- drugs used for gender-affirming care
- drugs used for members less than 21 years of age due to medical necessity (EPSDT)
- drugs used for members less than 21 years of age (EPSDT) such as Arazlo, Aplenzin, Cabtreo topical gel, Xifaxan 550 mg, Jublia, Tasmar, Zelapar, Relistor, Trulance, Bryhali, Duobrii, Siliq, Uceris rectal foam, or Luzu cream

Coverage Guidelines

Authorization of requested drug therapy may be approved when the following criteria have been met:

Gender-Affirming Care

1. There are no P&T-approved (Pharmacy & Therapeutic Committee) coverage guideline(s) for the requested drug and indication. If there are guideline(s) for the requested drug and indication, the request must be reviewed against the criteria listed on those guideline(s) first, as applicable
2. Documentation of a severe and persistent or widespread condition
3. Rationale or documentation of no other available treatment options (pharmacological or non-pharmacological) for **ONE** of the following:
    a. An agent for the reduction of hair growth in a person with male sex assigned at birth/biologic male (transgender male to female)
    b. **BOTH** of the following:
        i. The provider attests the drug is necessary to the member's identity
        ii. Documentation that the condition to be treated is negatively affecting the member's life as a transgender individual

Medical Necessity for ages <21 years old (EPSDT)

1. There are no P&T-approved (Pharmacy & Therapeutic Committee) coverage guideline(s) for the requested drug and indication. If there are guideline(s) for the requested drug and indication, the request must be reviewed against the criteria listed on those guideline(s) first, as applicable
2. Appropriate diagnosis
3. Member is less than 21 years of age

4. **ONE** of the following:
    a. Medical records documenting an inadequate response, adverse reaction, or contraindication to **ALL** available appropriate formulary alternatives and/or drugs that are considered standard of care when available (required documentation of drug name, dose, duration of therapy, and reason for failure or discontinuation)
    b. Member has condition for which there are no other formulary alternatives
    c. For combination drugs, documentation of an inadequate response, adverse reaction, or contraindication to individual ingredients used together when available
    d. Prescriber is requesting drug due to a drug shortage (must document drug shortage and anticipated duration of the shortage)

Requests for Arazlo, Aplenzin, Xifaxan 550 mg, Jublia, Tasmar, Zelapar, Relistor, Trulance, Bryhali, Duobrii, Siliq, Uceris rectal foam, Luzu cream, ***member is less than 21 years of age*** *and must meet the drug-specific criteria listed below:*

1. There are no P&T-approved (Pharmacy & Therapeutic Committee) coverage guideline(s) for the requested drug and indication. If there are guideline(s) for the requested drug and indication, the request must be reviewed against the criteria listed on those guideline(s) first, as applicable
2. **ONE** of the following:
    a. **Arazlo (tazarotene 0.045% lotion)**, all of the following:
        1. Diagnosis of **ONE** of the following:
            a. Acne (grade II or greater)
            b. Cutaneous warts
            c. Folliculitis/pseudofolliculitis (razor bumps/shave bumps)
        2. Medical records documenting inadequate response or an adverse reaction to a topical tretinoin agent and topical tazarotene agent
        3. Member must meet the above criteria and the prescriber must also submit documentation of trials of alternatives with rebate or clinical rationale for use of a non-rebate product
    b. **Aplenzin (bupropion hydrobromide extended-release)**, all of the following:
        1. Diagnosis of **ONE** of the following:
            a. Anxiety disorder
            b. Bipolar disorder
            c. Depressive disorder
            d. Obsessive-compulsive disorder
            e. Panic disorder
            f. Post-traumatic stress disorder
            g. Other psychiatric or neurologic condition requiring treatment with an antidepressant (i.e., psychotic disorder, neuropathic pain)
        2. Member is ≥ 18 and < 21 years of age
        3. Medical records documenting an inadequate response (defined as ≥ 4 weeks of therapy) or adverse reaction to bupropion XL at an equivalent dose to the requested product
        4. Requested quantity is ≤ 1 unit/day
        5. Member must meet the above criteria and the prescriber must also submit documentation of trials of alternatives with rebate or clinical rationale for use of a non-rebate product
    c. **Cabtreo (clindamycin, adapalene, benzoyl peroxide) topical gel 1.2/0.15/3.1%**, all of the following:

1. Diagnosis of ONE of the following:
    a. Acne (grade II or greater)
    b. folliculitis/pseudofolliculitis (razor bumps/shave bumps)
    c. hidradenitis suppurativa
    d. rosacea
2. Medical necessity for the combination product instead of the commercially available separate agents
3. Member must meet the above criteria and the prescriber must also submit documentation of trials of alternatives with rebate or clinical rationale for the use of a non-rebate product

d. **Xifaxan (rifaximin) 550 mg** for **ONE** of the following indications:
    1. Diagnosis of hepatic encephalopathy (or "high ammonia levels"), and all of the following:
        a. Member is ≥ 18 and < 21 years of age
        b. Inadequate response, adverse reaction or contraindication to lactulose
        c. Requested quantity is ≤ 2 unit/day
        d. Member must meet the above criteria and the prescriber must also submit documentation of trials of alternatives with rebate or clinical rationale for use of a non-rebate product
    2. Diagnosis of irritable bowel syndrome (IBS) with diarrhea, and all of the following:
        a. Member is ≥ 18 and < 21 years of age
        b. Inadequate response or adverse reaction to **THREE** or contraindication to **ALL** of the following:
            i. Bile acid sequestrant
            ii. Bismuth subsalicylate
            iii. Bulk-forming agent
            iv. Diphenoxylate/atropine
            v. Loperamide
            vi. TCAs
        c. Appropriate dosing (550 mg three times daily for 14 days)
        d. Member must meet the above criteria and the prescriber must also submit documentation of trials of alternatives with rebate or clinical rationale for use of a non-rebate product
    3. Diagnosis of small intestinal bacterial overgrowth (SIBO), and all of the following:
        a. Member is ≥ 12 and < 21 years of age
        b. Inadequate response or adverse reaction to **ONE** or contraindication to **ALL** of the following:
            i. Amoxicillin-clavulanate
            ii. Ciprofloxacin
            iii. Doxycycline
            iv. Metronidazole
            v. Neomycin
            vi. Norfloxacin
            vii. Tetracycline
            viii. Trimethoprim/sulfamethoxazole
        c. Appropriate dosing (550 mg three times daily for 14 days)

d. Member must meet the above criteria and the prescriber must also submit documentation of trials of alternatives with rebate or clinical rationale for use of a non-rebate product

e. **Jublia (efinaconazole)**, all of the following:
    1. Diagnosis of onychomycosis
    2. **ONE** of the following:
        a. Inadequate response or adverse reaction to itraconazole **OR** terbinafine oral tablets
        b. **BOTH** of the following:
            i. Medical necessity for topical formulation
            ii. Inadequate response (defined as ≥ 24 consecutive weeks of therapy) or adverse reaction to ciclopirox nail solution
        c. Contraindication to **ALL** of the following:
            i. Ciclopirox nail solution
            ii. Itraconazole oral therapy
            iii. Terbinafine oral tablets
        d. Member must meet the above criteria and the prescriber must also submit documentation of trials of alternatives with rebate or clinical rationale for use of a non-rebate product

f. **Tasmar (tolcapone)** – brand name only, all of the following:
    1. Diagnosis of Parkinson's disease
    2. Member is concurrently taking carbidopa/levodopa
    3. Inadequate response, adverse reaction, or contraindication to entacapone **AND** Ongentys (opicapone)
    4. Member must meet the above criteria and the prescriber must also provide **BOTH** of the following:
        a. Medical records documenting an inadequate response or adverse reaction to the generic tolcapone
        b. Trials of alternatives with rebate or clinical rationale for use of a non-rebate product

g. **Zelapar (selegiline orally disintegrating tablet)**, all of the following:
    1. Diagnosis of Parkinson's disease
    2. Member is concurrently taking carbidopa/levodopa
    3. Medical necessity for the ODT formulation instead of conventional formulations (e.g., swallowing disorder or dysphagia)
    4. Member is not utilizing other solid oral formulations
    5. Requested quantity is ≤2 units day
    6. Member must meet the above criteria and the prescriber must also submit documentation of trials of alternatives with rebate or clinical rationale for use of a non-rebate product

h. **Relistor (methylnaltrexone)** for **ONE** of the following indications:
    1. Diagnosis of OIC with advanced illness receiving palliative care, and all of the following:
        a. Member is ≥ 18 and < 21 years of age
        b. Appropriate dosing
        c. Inadequate response, adverse reaction, or contraindication to **ONE** agent from **THREE** of the four traditional laxative therapy classes
            i. Bulk forming laxatives

ii. Osmotic laxatives
iii. Saline laxatives
iv. Stimulant laxatives

d. For the injection formulation, medical necessity for the requested formulation instead of tablet formulation
e. Member must meet the above criteria and the prescriber must also submit documentation of trials of alternatives with rebate or clinical rationale for use of a non-rebate product

2. Diagnosis of OIC with chronic non-cancer pain, and all of the following:
    a. Member is ≥ 18 and < 21 years of age
    b. Appropriate dosing
    c. Inadequate response, adverse reaction, or contraindication to **ONE** agent from **THREE** of the four traditional laxative therapy classes
        i. Bulk forming laxatives
        ii. Osmotic laxatives
        iii. Saline laxatives
        iv. Stimulant laxatives
    d. Inadequate response, adverse reaction, or contraindication to Movantik **AND** Symproic
    e. Inadequate response, adverse reaction, or contraindication to **ONE** or contraindication to Linzess **AND** lubiprostone
    f. For the injection formulation, medical necessity for the requested formulation instead of tablet formulation
    g. Member must meet the above criteria and the prescriber must also submit documentation of trials of alternatives with rebate or clinical rationale for use of a non-rebate product

i. **Trulance (plecanatide)**, all of the following:
    1. Diagnosis of CIC or IBS-C
    2. Medical necessity for exceeding quantity limit
    3. Member must meet the above criteria and the prescriber must also submit documentation of trials of alternatives with rebate or clinical rationale for use of a non-rebate product
j. **Bryhali (halobetasol),** all of the following:
    1. Diagnosis of plaque psoriasis
    2. Member is ≥ 18 and < 21 years of age
    3. **ONE** of the following:
        a. Inadequate response or adverse reaction to **ALL** topical corticosteroids of the same formulation and potency range available without prior authorization:
            i. Augmented betamethasone
            ii. Betamethasone dipropionate
            iii. Clobetasol propionate
            iv. Fluocinonide 0.1% cream
            v. Halobetasol
        b. Medical necessity for the requested formulation
    4. Member must meet the above criteria and the prescriber must also submit documentation of trials of alternatives with rebate or clinical rationale for use of a non-rebate product
k. **Duobrii (halobetasol/tazarotene)**, all of the following:

1. Diagnosis of plaque psoriasis
2. Member is ≥ 18 and < 21 years of age
3. Inadequate response or adverse reaction to **ONE** superpotent or potent topical corticosteroid available without prior authorization (e.g., augmented betamethasone, betamethasone propionate, clobetasol propionate, halobetasol etc)
4. Medical necessity for the combination product instead of the commercially available separate agents
5. Member must meet the above criteria and the prescriber must also submit documentation of trials of alternatives with rebate or clinical rationale for use of a non-rebate product

l. **Siliq (brodalumab)** for **ONE** of the following indications:
   1. Diagnosis of moderate to severe plaque psoriasis, and all of the following:
      a. **ONE** of the following:
         i. Inadequate response or adverse reaction to **ONE** or contraindication to **ALL** conventional therapies:
            1. Topical agent
            2. Phototherapy
            3. Systemic agent
         ii. Inadequate response or adverse reaction to **ONE** biologic DMARD that is FDA-approved for plaque psoriasis
      b. Appropriate dosing
      c. **BOTH** of the following:
         i. Inadequate response, adverse reaction, or contraindication to **ALL** of the following:
            1. Stelara
            2. Skyrizi
            3. Taltz
         ii. Inadequate response or adverse reaction to **ONE** or contraindication to **ALL** ant-TNF agents that are FDA-approved for plaque psoriasis
      d. Member must meet the above criteria and the prescriber must also submit documentation of trials of alternatives with rebate or clinical rationale for use of a non-rebate product
   2. Diagnosis of pityriasis rubra pilaris (PRP), and all of the following:
      a. Inadequate response or adverse reaction to **ONE** topical corticosteroid or contraindication to **ALL** topical corticosteroids
      b. Clinical rationale for use of the requested agent instead of Stelara and Taltz
      c. Member must meet the above criteria and the prescriber must also submit documentation of trials of alternatives with rebate or clinical rationale for use of a non-rebate product

m. **Uceris (budesonide rectal foam)** – brand name only, all of the following:
   1. Diagnosis of ulcerative colitis
   2. Member is ≥ 18 and < 21 years of age
   3. Inadequate response (defined as ≥3 weeks of therapy) or adverse reaction to **ONE** or contraindication to **BOTH** of the following:
      a. Hydrocortisone enema
      b. Hydrocortisone foam
   4. Member must meet the above criteria and the prescriber must also provide **BOTH** of the following:

a. Medical records documenting an inadequate response or adverse reaction to the generic budesonide rectal foam
b. Trials of alternatives with rebate or clinical rationale for use of a non-rebate product

Continuation of Therapy

Reauthorization requires physician documentation of continuation of therapy and the following criteria:

1. Medical records or pharmacy history supporting that the member has been successfully maintained and compliant on current drug therapy
2. Member had a positive therapeutic response to current drug therapy
3. Documentation of clinical rationale, or provider attestation, that a change in therapy would result in instability of the member's medical condition

Limitations

1. Initial and reauthorization approvals will be granted for the following:
    a. Gender affirming care: 12 months
    b. EPSDT: up to 12 months or until member's 21st birthday, whichever is sooner

References

N/A

Review History

9/13/23 – Created for P&T in response to the EPSDT requirement by MH where limitations and exclusions in 130 CMR 406.413(B) do not apply to medically necessary drug therapy for members under age 21. This was created to allow for consistent review for certain drugs. Effective 10/2/23

12/13/23 – Reviewed and updated for P&T. Policy was updated to reflect the change in regulation for coverage of cosmetic agents by adding "unless medically necessary". Procedures for reviewing gender-affirming care agents specified. This regulation change will broaden the scope of review beyond EPSDT. Proposed criteria approved by MH on 12/28/23. Effective 1/2/24

04/10/24 – Reviewed and updated for P&T. Updated criteria for Cosmetic or Hair Growth Agents due to Medical Necessity. Removed verbiage regarding medical necessity for non-gender-affirming care requests. Updated initial approval duration to 12 months. Effective 05/06/24

11/12/25 - Reviewed and updated for P&T. Updated criteria following the B&L update. Included drugs that require additional EPSDT review. Effective 10/15/25

3/11/26 – Reviewed and updated for P&T. Bausch and Lomb added Cabtreo to be available on the patient assistance program (PAP). EPDST (<21) review still applies for drugs that have PA with PAP available. Effective 4/1/26

6/10/26 – Reviewed and updated for P&T. Formatting updated. Updated approval durations to reflect 21st birthday. Effective 7/1/26