

Medical Necessity
Effective 10/15/2025

Plan	<input checked="" type="checkbox"/> MassHealth UPPL <input type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit		
Specialty Limitations	N/A		
Contact Information	Medical Benefit	Phone: 833-895-2611	Fax: 888-656-6671
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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) for Arazlo, Aplenzin, Xifaxan 550 mg, Jublia, Tasmar, Zelapar, Relistor, Trulance, Bryhali, Duobrii, Siliq, Uceris rectal foam, or Luzu cream

Per MassHealth regulations:

406.413: Limitations on Coverage of Drugs

(B) Drug Exclusions. The MassHealth agency does not pay for the following types of prescription or over-the-counter drugs or drug therapy.

1. Cosmetic. The MassHealth agency does not pay for any drug when used for cosmetic purposes or for hair growth, unless medically necessary.
2. Cough and Cold. The MassHealth agency does not pay for any drug used solely for the symptomatic relief of coughs and colds, including but not limited to, those that contain an antitussive or expectorant as a major ingredient, unless dispensed to a member who is a resident in a nursing facility or an intermediate care facility for the mentally retarded (ICF/MR).
3. Fertility. The MassHealth agency does not pay for any drug used to promote fertility.
4. Less-than-effective Drugs. The MassHealth agency does not pay for any drug products (including identical, similar, or related drug products) that the U.S. Food and Drug Administration has proposed, in a Notice of Opportunity for Hearing (NOOH), to withdraw from the market because they lack substantial evidence of effectiveness for all labeled indications.
5. Experimental and Investigational Drugs. The MassHealth agency does not pay for any drug that is experimental, medically unproven, or investigational in nature.
6. Drugs for Sexual Dysfunction. The MassHealth agency does not pay for any drug when used for the treatment of sexual dysfunction.

Coverage Guidelines

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

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. Requests for gender-affirming care drugs must meet **ALL** of the following:
 - i. Documentation of a severe and persistent or widespread condition
 - ii. Rationale or documentation of no other available treatment options (pharmacological or non-pharmacological) for **ONE** of the following:
 1. An agent for the reduction of hair growth in a person with male sex assigned at birth/biologic male (transgender male to female)
 2. **BOTH** of the following:
 - a. The provider attests the drug is necessary to the member's identity
 - b. Documentation that the condition to be treated is negatively affecting the member's life as a transgender individual
 - b. Requests for all other drugs due to medical necessity (**EPSDT**) must meet **ALL** of the following:
 - i. Appropriate diagnosis
 - ii. Member is less than 21 years of age
 - iii. **ONE** of the following:
 1. 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)
 2. Member has condition for which there are no other formulary alternatives
 3. For combination drugs, documentation of an inadequate response, adverse reaction, or contraindication to individual ingredients used together when available
 4. Prescriber is requesting drug due to a drug shortage (must document drug shortage and anticipated duration of the shortage)
 - c. Requests for Arazlo, Aplenzin, Xifaxan 550 mg, Jublia, Tasmir, Zelapar, Relistor, Trulance, Bryhali, Duobrii, Siliq, Uceris rectal foam, Luzu cream, must meet the drug-specific criteria due to EPSDT listed below:
 - i. **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
 - ii. **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
- iii. **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
- iv. **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
- v. **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
- vi. **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
- vii. **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
- viii. **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
- ix. **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
- x. **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
- xi. **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
- xii. **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 approvals will be granted for 12 months.
2. Reauthorizations will be granted for 12 months.

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

