STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
BUREAU FOR MEDICAL SERVICES

Office of Pharmacy Services
Prior Authorization Criteria

denotes change in current criteria

denotes new criteria

Evrysdi (Risdiplam)

Evrysdi *is a survival of motor neuron 2 (SMN2) splicing modifier indicated for the treatment of spinal muscular atrophy (SMA) in patients 2 months of age and older.*

CRITERIA FOR APROVAL:

1. Evrysdi must be prescribed by, or in consultation with, a neurologist or a neuromuscular specialist in the treatment of spinal muscular atrophy; **AND**

2. Documentation must be submitted showing the patient has a diagnosis of Spinal Muscular Atrophy (SMA) confirmed by genetic testing; **AND**

3. Patient is 2 months of age or older; **AND**

4. The patient does not have hepatic impairment; **AND**

5. The patient must not have advanced SMA and does not require the use of permanent ventilation or tracheostomy; **AND**

6. Females of childbearing potential should have a negative pregnancy test collected within 30 days prior to the initiation of therapy. All patients must commit to use effective contraception during treatment and for at least 1 month after the last dose and the provider should monitor/counsel patients regarding pregnancy risk; **AND**

7. Patient is not concurrently being treated with Spinraza; **AND**

8. Patient has not received prior treatment with Zolgensma; **AND**

9. Obtain and provide documentation of a baseline assessment motor milestone score from at least ONE of the following assessments:

1- Hammersmith Functional Motor Scale Expanded (HFMSE)
2- Hammersmith Infant Neurologic Exam (HINE)
3- Upper limb module (ULM) score or Revised upper limb module (RULM) score
4- Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND)
5- Six-minute walk test
6- Bayley Scales of Infant and Toddler development Third Ed. (BSID-III)
7- Motor Function Measure-32 Items (MFM-32)

CONTINUATION OF THERAPY:

1. Patient must continue to meet all initial prior authorization criteria; AND

2. Documented evidence must be submitted showing clinically significant improvement in SMA associated symptoms, such as lack of progression, stabilization, or decreased decline in motor function, as compared to the natural history trajectory of the disease by submission of medical records with the most recent results (**≤ 6 month prior to request**) documenting a positive clinical response from pretreatment baseline status to Evrysdi therapy as demonstrated by at least **one** of the following assessments:

1- Hammersmith Functional Motor Scale Expanded (HFMSE)
2- Hammersmith Infant Neurologic Exam (HINE)
3- Upper limb module (ULM) score or Revised upper limb module (RULM) score
4- Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND)
5- Six-minute walk test
6- Bayley Scales of Infant and Toddler development Third Ed. (BSID-III)
7- Motor Function Measure-32 Items (MFM-32)

Approval Duration: Initial approval will be granted for 6 months and continuation will be granted for 12 months.

Breztri Aerosphere (budesonide/glycopyrrolate/formoterol)

- (budesonide 160 mcg/glycopyrrolate 9 mcg/formoterol 4.8 mcg)

- Preferred options available:

Bevespi- glycopyrrolate/formoterol AND Pulmicort Flexhaler- Budesonide

Breztri may be prior authorized for patients currently established on the individual components for at least 30 days.

THERAPEUTIC DRUG CLASS		
PREFERRED AGENTS	**NON-PREFERRED AGENTS**	**PA CRITERIA**
ANTICHOLINERGIC-BETA AGONIST-GLUCOCORTICOID COMBINATIONS		
	TRELEGY ELLIPTA (fluticasone/umeclidinium/vilanterol)* BREZTRI AEROSPHERE* (budesonide/glycopyrrolate/formoterol)	* Trelegy Ellipta may be prior authorized for patients currently established on the individual components for at least 30 days. *Breztri Aerosphere may be prior authorized for patients currently established on the individual components for at least 30 days.

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Palforzia

Palforzia *is an oral immunotherapy indicated for the mitigation of allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanuts. Palforzia is approved for use in patients with a confirmed diagnosis of peanut allergy.*

Palforzia is not indicated for the emergency treatment of allergic reactions, including anaphylaxis.

CRITERIA FOR APROVAL:

1. Patient age must be ≥ 4 years and ≤ 17 years for initial dose escalation or ≥ 4 years for up-dosing and maintenance; **AND**

2. Palforzia must be prescribed by, or in conjunction with, an allergist or immunologist; **AND**

3. Patient must have a diagnosis of a peanut allergy confirmed by a serum immunoglobulin E (IgE) to peanut ≥0.35 kUA/L (kilos of allergen-specific units per liter within the past 12 months); **and/or** a skin prick test (SPT) to peanuts ≥3 mm compared to control; **AND**

4. Palforzia must be used in conjunction with a peanut-avoidant diet; **AND**

5. Patient must NOT have a recent history of uncontrolled asthma, eosinophilic esophagitis, or other eosinophilic gastrointestinal disease; **AND**

6. Prescriber, pharmacy, and patient must be registered with the REMS Program; **AND**

7. The patient must be prescribed injectable epinephrine, be given training and instruction on its appropriate use, and be instructed to seek immediate medical attention upon being used.

Approval Duration:

Initial approval will be granted for 6 months and includes approval for initial dose escalation and Up Dosing. *Approval for Up Dosing may be extended if the patient was unable to tolerate all the dose levels at 2-week intervals.

Maintenance Dosing approval (300mg daily) will be initially granted for 6 months upon which pharmacy records will be evaluated to assess compliance with once daily therapy and ensure no level was missed during Up Dosing. Documentation must be provided attesting that the patient has not experienced any treatment restricting adverse events (such as systemic allergic reactions, severe anaphylaxis). 12-month authorizations may be granted thereafter upon evaluation of compliance and prescriber attestation that patient is not experiencing any adverse events/reactions to Palforzia.

Entocort EC, Ortikos

Entocort EC and Ortikos may only be authorized if the patient has a documented allergy or intolerance to the generic budesonide 3mg 24-hour capsules.

CROHNS DISEASE ORAL STEROIDS		
ORAL		
budesonide ER capsule (generic Entocort EC)	ENTOCORT EC (budesonide)* ORTIKOS (budesonide)*	*Please see the following PDL classes for PDL status of additional agents used for induction and remission (Cytokine and CAM Antagonists/ Immunosuppressives, Oral/ Ulcerative Colitis Agents) *Entocort EC and Ortikos may only be authorized if the patient has a documented allergy or intolerance to the generic budesonide 3mg 24-hour capsules.

Lubiprostone

Lubiprostone- may only be authorized with a documented allergy or intolerance to Amitiza.

IRRITABLE BOWEL SYNDROME/SHORT BOWEL SYNDROME/SELECTED GI AGENTS CL		
CLASS PA CRITERIA: All agents are approvable only for patients age eighteen (18) and older. **See below for additional sub-class criteria.**		
CONSTIPATION		
AMITIZA (lubiprostone) MOVANTIK (naloxegol) LINZESS (linaclotide)	LINZESS 72 mcg (linaclotide) lubiprostone capsule* MOTEGRITY (prucalopride) RELISTOR INJECTION (methylnaltrexone) RELISTOR TABLET (methylnaltrexone) SYMPROIC (naldemedine) TRULANCE (plecanatide) ZELNORM (tegaserod maleate)	All agents in this subclass require documentation of the current diagnosis and evidence that the patient has failed to find relief with dietary modification and a fourteen (14) day trial of an osmotic laxative. No agent shall be approved to treat opioid induced constipation (OIC) without evidence of at least 90-days of opioid use preceding the request. Continuation of coverage shall be granted with evidence of continuous and concurrent opioid use. **Agents may be authorized only for their FDA-approved labeled indication. The following agent-specific criteria shall also apply, unless one (1) of the exceptions on the PA form is present:** **Motegrity** requires a 30-day trial of both Amitiza and Linzess. **Relistor** and **Symproic** are indicated for OIC and require thirty (30) day trials of both Movantik and Amitiza. **Trulance** requires thirty (30) day trials of both Amitiza and Linzess, however for the indication of IBS-C in males, a trial of Amitiza is not required. **Linzess 72mcg** may only be approved for a diagnosis of

THERAPEUTIC DRUG CLASS		
PREFERRED AGENTS	**NON-PREFERRED AGENTS**	**PA CRITERIA**
		chronic idiopathic constipation (CIC) AND for those who cannot tolerate the 145mcg dose. **Zelnorm** is indicated for females < 65 years of age diagnosed with irritable bowel syndrome with constipation (IBS-C) AND requires thirty (30) day trials of Amitiza and Linzess. **Lubiprostone- may only be authorized with a documented allergy or intolerance to Amitiza.**

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Oriahnn

Oriahnn *is a combination of elagolix, a gonadotropin-releasing hormone (GnRH) receptor antagonist, estradiol, an estrogen, and norethindrone acetate, a progestin, indicated for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women.*

CRITERIA FOR APROVAL:

1. Patient must be a premenopausal woman diagnosed with heavy menstrual bleeding associated with uterine leiomyomas (fibroids); **AND**

2. Patient must be within the age range as recommended by the FDA label; **AND**

3. Patient must not be pregnant; **AND**

4. Patient must not be diagnosed with osteoporosis; AND

5. Patient has failed a 90-day trial with one agent from ONE the following categories (unless contraindicated):

    a. Combination Estrogen/Progestin contraceptives
    b. Progestin therapy (oral, transdermal, vaginal ring, IUD, or injections)
    c. Tranexamic acid

Initial prior authorization will be for 90 days. Continuation of coverage requires documentation of clinically significant improvement in symptoms as compared to that seen using previous therapy.

Maximum length of therapy is limited to 24 months due to the risk of continued bone loss, which may not be reversible.

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Enspryng

Enspryng (Satralizumab) *is an antagonist of the interleukin-6 (IL-6) receptor. Satralizumab is presumed to inhibit IL-6-mediated signaling through binding to soluble and membrane-bound IL-6 receptors. It is indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive.*

CRITERIA FOR APROVAL:

1. Patient must have a diagnosis of neuromyelitis optica spectrum disorder (NMOSD) confirmed by an anti-aquaporin-4 (AQP4) antibody positive blood serum test; **AND**

2. Patient must have one of the core clinical characteristics from the following:

    a. Optic neuritis,
    b. Acute myelitis,
    c. Area postrema syndrome: episode of otherwise unexplained hiccups or nausea and vomiting,
    d. Acute brainstem syndrome,
    e. Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions, or
    f. Symptomatic cerebral syndrome with NMOSD-typical brain lesions; **AND**

3. Patient must be 18 years of age or older; **AND**

4. Enspryng must be prescribed by, or in consultation with, a neurologist; **AND**

5. Patient has a history of ≥ 1 relapses that required rescue therapy within the past 12 months or 2 ≥ relapses that required rescue therapy in the past two years, at least one of which must have occurred in the previous year; **AND**

6. Patient has an Expanded Disability Status Score (EDSS) of ≤ 6.5; **AND**

7. The patient is currently receiving or has had a previous 8-week trial with, contraindication to, or intolerance to at least **ONE** of the following systemic therapies: Azathioprine, Corticosteroids, Mycophenolate mofetil or Rituximab.

8. Patient must NOT have an active hepatitis B infection; **AND**

9. Patient must NOT have active or untreated latent tuberculosis; **AND**

10. Enspryng will not be concurrently used with Soliris, Uplizna or Rituximab.

Initial approval will be for 6 months.

Continuation of therapy:

May be granted if documentation is provided showing patient achieves or maintains a positive clinical response with Enspryng demonstrated by reduction in relapse rate, reduction in symptoms (such as pain, fatigue, motor function), or a slowing progression in symptoms.
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Continuation approval will be for 12 months.

Analgesics, Narcotics Long-Acting

Current criteria:

**Methadone, oxycodone ER and oxymorphone ER will be authorized without a trial of the preferred agents if a diagnosis of cancer is submitted.

Proposed criteria: *(removal of oxycodone ER and oxymorphone ER because Xtampza ER is preferred)*

**Methadone will be authorized without a trial of the preferred agents if a diagnosis of cancer is submitted.

PREFERRED AGENTS	NON-PREFERRED AGENTS	PA CRITERIA
ANALGESICS, NARCOTIC LONG ACTING (Non-parenteral)[AP]		
CLASS PA CRITERIA: Non-preferred agents require six (6) day trials of two (2) chemically distinct preferred agents **AND** a six (6) day trial of the generic form of the requested non-preferred agent (if available) before they will be approved, unless one (1) of the exceptions on the PA form is present. If no generic form is available for the requested non-preferred brand agent, then another generic non-preferred agent must be trialed instead. **NOTE: All long-acting opioid agents require a prior authorization for children under 18 years of age.** Requests must be for an FDA approved age and indication and specify previous opioid and non-opioid therapies attempted.		
BUTRANS (buprenorphine) fentanyl transdermal 12, 25, 50, 75, 100 mcg/hr morphine ER tablets tramadol ER tablets (generic Ultram ER) XTAMPZA ER (oxycodone)	ARYMO ER (morphine sulfate) BELBUCA (buprenorphine buccal film)* buprenorphine patch (all labelers including 00093) CONZIP ER (tramadol) fentanyl transdermal 37.5, 62.5, 87.5 mcg/hr hydromorphone ER HYSINGLA ER (hydrocodone) KADIAN (morphine) methadone** MORPHABOND ER (morphine sulfate) morphine ER capsules (generic for Avinza) morphine ER capsules (generic for Kadian) MS CONTIN (morphine) NUCYNTA ER (tapentadol) oxycodone ER** OXYCONTIN (oxycodone) oxymorphone ER** tramadol ER (generic Conzip ER)*** ULTRAM ER (tramadol) ZOHYDRO ER (hydrocodone)	*Belbuca prior authorization requires manual review. Full PA criteria may be found on the PA Criteria page by clicking the hyperlink. **Methadone will be authorized without a trial of the preferred agents if a diagnosis of cancer is submitted. ***Tramadol ER (generic Conzip) requires a manual review and may be authorized for ninety (90) days with submission of a detailed treatment plan including anticipated duration of treatment and scheduled follow-ups with the prescriber.

Suboxone Policy:

-removal of the approval of buprenorphine only products during pregnancy

Current criteria:

5) Buprenorphine tablets may only be approved for use during pregnancy or in the case of a well-documented and clinically verified life-threatening allergy to naloxone*; **AND**

Naloxone allergy documentation MUST include a detailed description of symptoms. (Life threatening allergic reactions are generally considered to be anaphylactic in nature, Stevens-Johnson syndrome or DRESS).

Proposed criteria:

-removal of “may only be approved for use during pregnancy” (change to approved only by medical director on a case-by-case basis)

5) Buprenorphine tablets may only be approved by the Medical Director on a case-by-case basis or with a clinically verified life-threatening allergy to naloxone*; **AND**

Naloxone allergy documentation MUST include a detailed description of symptoms. (Life threatening allergic reactions are generally considered to be anaphylactic in nature, Stevens-Johnson syndrome or DRESS).