ATTACHMENT A – PA Criteria Changes

1. **Antibiotics, GI & Related Agents** – (Dificid) –Criteria has been updated to match current guidelines by removing the requirement for metronidazole.

2. **Antipsychotics, Atypical**- Change in class criteria to now read: "Non-preferred agents require thirty (30) day trials of two (2) preferred agents, including the generic formulation of the requested agent (if available), before they will be approved unless one (1) of the exceptions on the PA form is present. All trials must be at the maximum recommended dose for the diagnosis provided before they would be considered a failure unless an adverse reaction is documented necessitating a change in therapy."

   For Latuda: ***For the indication of bipolar depression only, prior authorization of Latuda requires failure of a 30-day trial of quetiapine and failure of a 30-day trial with a combination of olanzapine + fluoxetine. All trials must be at the maximum recommended dose for the diagnosis provided before they would be considered a failure unless an adverse reaction is documented necessitating a change in therapy.
   All other indications follow class criteria. Patients already stabilized on Latuda shall be grandfathered.

3. **Hypoglycemics, GLP-1 Agonists & Hypoglycemics, SGLT2 Inhibitors –** Change in class criteria to now read:
   - Initial starts require a diagnosis of Type 2 Diabetes and an A1C taken within the last 30 days reflecting the patient's current and stabilized regimen.
   - No agent in this class shall be approved except as add on therapy to a regimen consisting of at least one (1) other agent prescribed at the maximum tolerable dose for at least 90 days.
   - Re-authorizations require continued maintenance on a regimen consisting of at least one (1) other agent at the maximum tolerable dose AND an A1C of ≤8%.

4. **Toujeo Solostar and Toujeo Max Solostar** – Change in class criteria to now read:

   Tresiba U-100 will be authorized only for patients who have demonstrated at least a 6-month history of compliance on preferred long-acting insulin and who continue to have regular incidents of hypoglycemia.

   Tresiba U-200, Toujeo Solostar and Toujeo Max Solostar will **only** be approved for patients who require once-daily doses of at least 60 units of long-acting insulin and have demonstrated at least a 6-month history of compliance on preferred long-acting insulin and who continue to have regular incidents of hypoglycemia.

5. **Rhopressa** - Change in class criteria to now read: Prior authorization of any agent in this sub-class requires a trial of at least one (1) preferred agent from all other sub-classes.

6. **Sublocade** – Adding criteria to now read: "Sublocade is approvable only on appeal and requires medical reasoning as to why the clinical need cannot be met with a preferred product."

7. **Sedative Hypnotics** – Change in class criteria to now read: "Non-preferred agents require thirty (30) day trials of all preferred agents in **BOTH** sub-classes before they will be approved, unless one (1) of the exceptions on the PA form is present. All agents except melatonin will be limited to fifteen (15) tablets in a thirty (30) day period. NOTE: WV Medicaid covers melatonin up to a maximum dose of 9 mg/day without a PA."

   Melatonin has been added to the PDL as a preferred agent.

8. **Stimulants and Related Agents -** Change in class criteria to now read: A PA is required for adults eighteen (18) years of age or older. PLEASE NOTE: Requests for amphetamine or methylphenidate IR + ER combination therapy must be for the same active ingredient in the same salt form, if available.
   Non-preferred agents require a thirty (30) day trial of at least one preferred agent in the same subclass and with a similar duration of effect and mechanism of action, unless one (1) of the exceptions on the PA form is present. **NOTE**: Non-preferred agents will NOT be "grandfathered" for adults. Children under the age of 18 may continue their current therapy until the end of the school year after which they will be required to switch to a preferred agent.

9. **Kapvay/Clonidine ER** – Remove subclass criteria and use the class criteria instead.

10. **Aimovig – NEED THE FINAL COPY**

11. **Austedo / Ingrezza – see below**

12. **Orlissa – see below**

13. **Xolair – see below**

Office of Pharmacy Service
Prior Authorization Criteria

Austedo® (deutetrabenazine)
Prior Authorization Request Form

AUSTEDO is a vesicular monoamine transporter 2 (VMAT2) inhibitor indicated for the treatment of adults with chorea associated with Huntington's disease and for the treatment of tardive dyskinesia in adults.

Initial* Prior Authorization Criteria:

- The patient must be within the age range as recommended by the FDA label; AND
- Patient must have been evaluated and found not to be suicidal or have untreated/undertreated depression; AND
- Patient must not be taking an MAOI (at least 14-days post-therapy), reserpine (must be >20 days post therapy) or any other concurrent VMAT2 inhibitor
- Prescriber must provide a brief description of the medical necessity of therapy by documenting all target symptoms and their impact on the patient's function and activities of daily living; **AND**

The following indication-specific criteria also apply:

I. Treatment of Chorea associated with Huntington's Disease:

1. Request must come from the treating neurologist; **AND**
2. All previous therapies must be documented along with their relative benefit. Unless contraindicated, the patient must have a documented 90-day trial of **amantadine** or **Xenazine (tetrabenazine)**.

II. Treatment of Tardive Dyskinesia (TD):

1. Request must come from the treating neurologist or psychiatrist; **AND**
2. Patient must provide a documented clinical diagnosis of tardive dyskinesia meeting DSM-V criteria including:
    a. Involuntary athetoid or choreiform movements
    b. History of treatment with a dopamine receptor blocking agent (DRBA) such as an antipsychotic or metoclopramide
    c. Symptom duration lasting at least 8 weeks

    AND
3. Prescriber must submit the results of an Abnormal Involuntary Movement Scale (AIMS) exam with every request for prior authorization of Austedo; **AND**

4. Prescriber must submit documentation of all other therapies attempted and their associated benefit **(including relevant AIMS scores)**. Unless contraindicated, these therapies must include a **90-day trial with at least one** of the following agents: **clonazepam**, **amantadine, or Xenazine** (tetrabenazine).

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

References

1.) Lexi-Comp drug monograph for Austedo (Reviewed 9/11/2018)
2.) Package insert for Austedo (last update 8/2017)
3.) Package insert for Xenazine (last update 9/2017)
4.) Abnormal Involuntary Movement Scale (AIMS) and Extrapyramidal Symptom Rating Scale (ESRS): cross-scale comparison in assessing tardive dyskinesia. Schizophr Res. 2005 Sep 15;77(2-3):119-28. Gharabawi GM[1], Bossie CA, Lasser RA, Turkoz I, Rodriguez S, Chouinard G.
5.) UpToDate Tardive Dyskinesia: Prevention and Treatment. Article last updated July 24, 2017
6.) American Academy of Neurology Evidence-based guideline: Treatment of tardive syndromes. July 29, 2013.
7.) Treatment of Huntington's Disease. Neurotherapeutics. 2014 Jan; 11(1): 153–160.
8.) American Academy of Neurology Evidence-based guideline: Pharmacologic treatment of chorea in Huntington disease. August 7, 2012.

Office of Pharmacy Service
Prior Authorization Criteria

Orilissa® (elagolix)

Effective 00/00/0000

Prior Authorization Request Form

Orilissa is a gonadotropin-releasing hormone (GnRH) receptor antagonist indicated for the management of moderate to severe pain associated with endometriosis.

Prior authorization requests for may be approved if the following criteria are met:

0. The patient must be within the age range as recommended by the FDA label; **AND**

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

2. Prescriber must document all previous therapies; AND

3. Patient must have had a 90-day trial (and failure to find significant relief) with an agent from each of the following categories:
    a. NSAIDs
    b. GnRH agonist
    c. Extended-cycle combined oral contraceptive
    d. Progestin therapy

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

References

1. Orilissa Package Insert (7/2018)
2. LexiComp monograph on Orilissa (reviewed 9/17/2018)
3. ACOG updates guideline on diagnosis and treatment of endometriosis. Am Fam Physician. 2011 Jan 1;83(1):84-85
4. Institute for Clinical and Economic Review Final Report Highlights Limitations in Evidence on Long-term Safety and Effectiveness of Elagolix for Endometriosis, Discusses Options for Insurance Coverage Criteria. August 3, 2018

Office of Pharmacy Service
Prior Authorization Criteria

Xolair® (Omalizumab)
Prior Authorization Request Form

Xolair is an anti-IgE antibody indicated for:

- *Moderate to severe persistent asthma in patients 6 years of age and older with a positive skin test or in vitro reactivity to a perennial aeroallergen and symptoms that are inadequately controlled with inhaled corticosteroids.*
- *Chronic idiopathic urticaria in adults and adolescents 12 years of age and older who remain symptomatic despite H1 antihistamine treatment.*

Prior authorization requests for Xolair may be approved if the following criteria are met:

For moderate to severe persistent asthma

1) Patient is six (6) years of age or older; **AND**
2) Must be prescribed by a board-certified pulmonologist or board-certified allergist; **AND**
3) Current body weight is between 20kg and 150kg; **AND**
4) If the patient currently smokes they must be enrolled in a smoking cessation program; **AND**
5) Patient is symptomatic despite receiving recommended first line treatments (including high dose inhaled corticosteroids + LABA) and exhibiting compliance with those treatments; **AND**
6) Patient has reacted positively to a perennial aeroallergen skin or blood test; **AND**
7) Patient must have an IgE level not less than 30 IU/ml or more than the Manufacturer's recommendation, based on weight. (The patient's weight and pretreatment serum IgE must be presented to review dosing).

For moderate to severe Chronic Idiopathic Urticaria:

1) Current diagnosis must be Chronic Idiopathic Urticaria, (documentation supporting diagnosis must be provided with PA request); **AND**
2) Patient is twelve (12) years of age or older; **AND**
3) Prescribed by a board-certified Allergist, Immunologist, or Dermatologist; **AND**
4) Contraindication to, or documented failure of, scheduled H-1 antihistamine at maximum tolerable dosing***** and leukotriene inhibitor therapy; **AND**
5) Evidence of an evaluation that excludes other medical diagnoses associated with chronic urticaria (supporting documentation must be provided with PA request).

* For CIU, intolerance/contraindication to maximum dosing of H-1 antihistamine must be clearly documented and justified on the prior authorization request. As-needed or "burst" therapies will not be considered as adequate therapy attempts.

Prior authorization requests for will be initially granted for three (3) months. Prior authorization will be granted for an additional twelve (12) months after receipt of documentation supporting clinical improvement from prior to initiating omalizumab.

References:

1) Xolair® (package insert) Genentech Inc. South San Francisco, CA. 5/2018
2) Lexi-Comp™ Xolair monograph and Clinical Consult™ application 9/182018.

3) Asthma Care – Guidelines from the National Asthma Education and Prevention Program (2012)
4) Global Initiative for Asthma – 2018 guidelines