denotes change in current criteria
denotes new criteria

Veozah (fezolinetant)

VEOZAH is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause.

CRITERIA FOR APPROVAL:

1. The patient has a diagnosis of menopause with moderate to severe vasomotor symptoms; **AND**

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

3. Documentation detailing the frequency and severity of the vasomotor symptoms must be provided; **AND**

4. The patient has had a 30-day trial of one hormone replacement therapy (HRT) agent (unless contraindicated) and has had a 30-day trial of ONE non-hormonal therapies (such as an SSRI, SNRI, gabapentin, pregabalin or clonidine) which failed to provide sufficient relief OR if a hormonal therapy cannot be tolerated, 2 30-day trials of non-hormonal therapies…; **AND**

5. Patient must have baseline liver function tests prior to initiating therapy* and every month for the first three months after patients start treatment, and then at months 6 and 9 of treatment; **AND**

6. Patient does not have severe renal impairment or end-stage renal disease.

Initial approvals may be authorized for 90 days. Further approvals may be granted for 1 year after all the continuation of therapy criteria has been met.

Do not start VEOZAH if concentration of ALT or AST is equal to or exceeds two times the ULN

CONTINUATION OF THERAPY CRITERIA:

1) Patient continues to meet all initial approval criteria; **AND**
2) Demonstrate continued documented compliance; **AND**
3) Documentation of positive clinical response to therapy must be provided (such as decrease in frequency of symptoms and/or improvement in severity of vasomotor symptoms); **AND**
4) Patient has not experienced any treatment-restricting adverse effects (e.g., ALT or AST > 3 times the ULN).

denotes change in current criteria
denotes new criteria

Wegovy (semaglutide injection)

Wegovy is a glucagon-like peptide-1 (GLP-1) receptor agonist indicated in combination with a reduced calorie diet and increased physical activity to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established cardiovascular disease and either obesity or overweight. Wegovy is also indicated to reduce excess body weight and maintain weight reduction long term in adults and pediatric patients aged 12 years and older with obesity, and in adults with overweight in the presence of at least one weight-related comorbid condition.

Limitations of use: Coadministration with other semaglutide-containing products or with any other GLP-1 receptor agonist is not recommended

Agents used for the purpose of weight loss are typically a benefit exclusion. Coverage of Wegovy will only be considered for the secondary prevention of a cardiovascular event.

CRITERIA FOR APPROVAL:

1. Patient is 45 years of age or older; **AND**

2. The patient has a documented Body Mass Index (BMI) of 30 kg/m^2 or greater (date and results of the most recent BMI calculation are stated on the request); **AND**

3. Must be prescribed by, or in consultation with, a M.D./D.O. cardiologist, vascular surgeon or neurologist; **AND**

4. The patient has had at least ONE of the following:

    a) Prior myocardial infarction; **or**
    b) Prior stroke; **or**
    c) Symptomatic peripheral arterial disease (PAD) as demonstrated by one of the following:

        1. Formal vascular laboratory testing showing intermittent claudication with ankle-brachial systolic pressure index (ABI) of ≤ 0.85 at rest; or
        2. Peripheral revascularization procedure; or
        3. Amputation due to atherosclerotic disease; **AND**

5. The medication will be used as an adjunct to treatment and part of therapy which includes, but it not limited to:

    a) Optimized compliant pharmacotherapy for established cardiovascular disease and taking guideline- recommended measures for the secondary prevention of a major adverse cardiovascular event (MACE) which include:

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denotes new criteria

● Taking a statin at the maximally tolerated dose, ezetimibe, a PCSK9, or a combination of these medications as recommended and tolerated for patients with dyslipidemia;
● Optimizing medications to maintain the appropriate blood pressure goal for patients with hypertension (e.g. an ACE inhibitor or ARB)
● Taking a beta blocker for patients with a history of MI
● Taking anticoagulant or antiplatelet therapy for patients with coronary artery disease (CAD) or other high-risk diagnoses; **and**

b) The patient attests to behavioral modification including a reduced calorie diet and increased physical activity (documentation must be supplied with request); **AND**

6. HbA1c level taken within the last 6 months must be provided; **AND**

7. The patient does not have any of the following:

   a) Type 1, type 2 diabetes
   b) HbA1c $\geq$ 6.5%
   c) New York Heart Association class IV heart failure; **AND**

8. The medication will not be used with other GLP-1 agonist agents.

Initial approvals may be authorized for 90 days. Further approvals may be granted for 6-months after all the continuation of therapy criteria has been met.

CONTINUATION OF THERAPY CRITERIA:

1. Patient continues to meet all initial approval criteria; **AND**
2. Demonstrate continued documented compliance; **AND**
3. Renewal PA requests require the patient to be taking an appropriate maintenance dose such as 1.7mg or 2.4 mg per week. If the dose is 1.7mg dose is intolerable, medication should be discontinued.

denotes change in current criteria
denotes new criteria

Winrevair (sotatercept-csrk)

WINREVAIR is an activin signaling inhibitor indicated for the treatment of adults with pulmonary arterial hypertension (PAH, WHO Group 1) to increase exercise capacity, improve WHO functional class (FC) and reduce the risk of clinical worsening events.

CRITERIA FOR APPROVAL:

1. The patient has a diagnosis of WHO Group 1 PAH which is confirmed by the results of a documented (chart notes and catheterization laboratory reports) right heart catherization; **AND**

2. Symptomatic PAH classified as WHO Functional Class (FC) II, III or IV; **AND**

3. Patient is within the age range as recommended by the FDA label; **AND**

4. Must be prescribed by, or in consultation with, a M.D./D.O. cardiologist or pulmonologist; **AND**

5. Patient is currently receiving at least **TWO** other PAH therapies from the following different pharmacologic categories each for > 60 days:

    a) phosphodiesterase type 5 inhibitors (PDE5i), or
    b) endothelin receptor antagonists (ERAs), or
    c) soluble guanylate cyclase stimulator (sGCs), or
    d) prostacyclins.

Initial approvals may be authorized for 90 days. Further approvals may be granted for 1 year after all the continuation of therapy criteria has been met.

CONTINUATION OF THERAPY CRITERIA:

1. Patient continues to meet all initial approval criteria; **AND**
2. Demonstrate continued documented compliance.

denotes change in current criteria
denotes new criteria

Xolair

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.*
- *Add-on maintenance treatment of nasal polyps in adults with inadequate response to nasal corticosteroids*
- *IgE-mediated food allergy in adult and pediatric patients aged 1 year and older for the reduction of allergic reactions (Type I), including anaphylaxis, that may occur with accidental exposure to one or more foods. To be used in conjunction with food allergen avoidance*

For IgE-mediated food allergy:

1. Patient is one year of age or older; **AND**

2. Must be prescribed by, or in consultation with a M.D./D.O. allergist or immunologist; **AND**

3. Patient is allergic to peanuts **AND** at least two other foods, including milk, egg, wheat, cashew, hazelnut, or walnut; **AND**

4. Documentation (reports with results) is provided of **ALL** the following:
    a. Positive skin prick test (≥4 mm wheal) to above foods; and
    b. Positive food specific IgE (≥6 kUA/L) to above foods at Screening or within three months of Screening; and
    c. Positive DBPCFC (food challenge) to above foods, defined as experiencing dose-limiting symptoms at a single dose of ≤ 100mg of peanut protein and ≤300 mg of food protein; **AND**

5. Baseline serum IgE level equal to or greater than 30 IU/mL; **AND**

6. The patient has a history of a severe (type 1) allergic reaction requiring an ER visit, or hospitalization **AND** they had a history of wheeze, angioedema, and/or hives/urticaria; **AND**

7. This reaction occurred within a short period of time following a known ingestion of the food; **AND**

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denotes new criteria

8. The prescriber deemed this reaction significant enough to require a prescription for an epinephrine auto-injector and has prescribed one; **AND**

9. Xolair will be used in conjunction with a food allergen avoidance diet; **AND**

10. The patient is not on another monoclonal antibody.

CONTINUATION OF THERAPY CRITERIA:

1. Patient continues to meet all initial approval criteria; **AND**

2. Demonstrate continued documented compliance.

denotes change in current criteria
denotes new criteria

Entresto sprinkle capsules

Entresto sprinkle capsules may be authorized for children 1 years of age up to age nine (9) who are unable to ingest solid dosage forms. Therapy may be authorized for older patients with clinical documentation indicating oral-motor difficulties or dysphagia.

denotes change in current criteria
denotes new criteria

Ingrezza/ Austedo- adding "in consultation with"

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

Initial* Prior Authorization Criteria:

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

- 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:

Treatment of Chorea associated with Huntington's Disease:

1. ~~Request must come from the treating neurologist~~ Must be prescribed by, or in consultation with, a M.D./D.O. neurologist; **AND**

2. Patient must have been evaluated and found not to be suicidal or have untreated/undertreated depression; **AND**

3. All previous therapies must be documented along with their relative benefit. Unless contraindicated, the patient must have a documented 90-day trial, which resulted in intolerance or inadequate treatment response, to **Xenazine (tetrabenazine)**.

Treatment of Tardive Dyskinesia (TD):

1. ~~Request must come from the treating neurologist or psychiatrist~~ Must be prescribed by, or in consultation with, a M.D./D.O. neurologist or psychiatrist; **AND**

2. Patient must provide a documented clinical diagnosis of tardive dyskinesia meeting DSM including:

    a. Involuntary athetoid or choreiform movements
    b. History of treatment with a dopamine receptor blocking agent (DRBA) such as an antipsychotic or metoclopramide

denotes change in current criteria
denotes new criteria

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 Ingrezza; **AND**

Prescriber must submit documentation of all other therapies attempted and their associated benefit **(including relevant AIMS scores)**.

***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.

Austedo (Deutetrabenazine) *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 not be taking an MAOI (at least 14-days post-therapy), reserpine (must be >20 days post therapy) or any other concurrent VMAT2 inhibitor; **AND**

- 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:

Treatment of Chorea associated with Huntington's Disease:

1. ~~Request must come from the treating neurologist~~ Must be prescribed by, or in consultation with, a M.D./D.O. neurologist; **AND**

2. Patient must have been evaluated and found not to be suicidal or have untreated/undertreated depression; **AND**

3. All previous therapies must be documented along with their relative benefit. Unless contraindicated, the patient must have a documented 90-day trial, which resulted in intolerance or inadequate treatment response, to **Xenazine (tetrabenazine)**.

denotes change in current criteria
denotes new criteria

Treatment of Tardive Dyskinesia (TD):

1. ~~Request must come from the treating neurologist or psychiatrist~~ Must be prescribed by, or in consultation with, a M.D./D.O. 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)**.

***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.