denotes change in current criteria
denotes new criteria

Hetlioz

Hetlioz (Tasimelteon) *is a melatonin receptor agonist.* ***Hetlioz capsules*** *are indicated for the treatment of Non 24-Hour Sleep-Wake Disorder (Non-24) in adults and for the treatment of nighttime sleep disturbances in Smith-Magenis syndrome patients ≥16 years of age.* ***Hetlioz LQ oral suspension*** *is indicated for treatment of nighttime sleep disturbances in Smith-Magenis syndrome patients 3 to 15 years of age.*

CRITERIA FOR APPROVAL:

1. Patient must have a diagnosis of either of the following:
    a. Non-24-Hour Sleep-Wake Disorder (Non-24) as confirmed by:
        1- An assessment of one physiologic circadian phase marker (e.g., measurement of urinary melatonin levels; or an assessment of core body temperature); **or**
        2- If an assessment of physiologic circadian phase marker cannot be done, the diagnosis must be confirmed by actigraphy performed for at least 1 week plus evaluation of sleep logs recorded for at least 1 month showing evidence of progressively shifting sleep-wake times; **AND**
        3- Symptoms are not related to sleep hygiene, substance, or medication use, or other neurological or mental disorders.
    b. Nighttime sleep disturbances in Smith-Magenis syndrome with a confirmed deletion 17p11.2 (cytogenetic analysis or microarray) or RAI1 gene mutation is identified; **AND**
2. ~~Patient is 18 years of age or older~~ The patient is within the age range as recommended by the FDA label; **AND**
3. ~~Documentation must be provided indicating that the patient is totally blind with absolutely **no** perception of light~~; **AND**
4. Hetlioz is prescribed by, or in consultation with, a physician who specializes in the treatment of sleep disorders; **AND**
5. ~~Patient must have documented 3-month trials and therapy failure with all chemically unique preferred and non-preferred non-benzodiazepine sedative hypnotic agents. Quantity limits may still apply (15 tabs/30 day period), but may be waived on appeal with this specific diagnosis and documentation of at least partial efficacy; **AND**~~
6. Patient has a clinically documented 6-month trial of continuous melatonin supplementation without relief of symptoms; **AND**

7. Patient must have a documented trial and therapy failure with 6 months of ramelteon.

Approval Duration:

Initial approval will be for 3 months.

Criteria for reauthorization:

1. Demonstrate continued documented compliance; **AND**

2. Documentation indicating that the patient has achieved adequate results with Hetlioz, such as entrainment, significant increases in nighttime sleep, and/or significant decreases in daytime sleep has been provided.

Continuation of therapy will be granted for 12 months.

Opzelura cream

Opzelura (Ruxolitinib) *is a topical Janus Kinase (JAK) Inhibitor indicated for short-term and noncontinuous chronic treatment of mild to moderate atopic dermatitis in immunocompetent patients ≥12 years of age whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.*

CRITERIA FOR APPROVAL:

1- Patient has a diagnosis of mild to moderate atopic dermatitis; **AND**

2- The patient is within the age range as recommended by the FDA label; **AND**

3- Prescribed by, or in consultation with, an allergist, immunologist, or dermatologist; **AND**

4- The affected body surface area is ≤20%; **AND**

5- The patient has had an inadequate treatment response, intolerance, or contraindication after a minimum of 30-day trials of each of the following:

   a. A medium to high potency topical corticosteroid*,
   b. Pimecrolimus or tacrolimus,
   c. Eucrisa (for mild atopic dermatitis) and Dupixent (for moderate atopic dermatitis).

*Trial of medium to high potency topical steroid is required unless the affected area involves sensitive areas such as the face, skin folds or genitals.

6- Opzelura will **NOT** be approved for use in combination with therapeutic biologics, other JAK inhibitors, or potent immunosuppressants such as azathioprine or cyclosporine.

Approval Duration:

Approval will be for 8 weeks.

NOTE: **"The use of pharmaceutical samples will not be considered when evaluating the members' medical condition or prior prescription history for drugs that require prior authorization."**

Austedo

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 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. 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 **~~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)**.

***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.

Xenazine

Xenazine (tetrabenazine) *is a vesicular monoamine transporter 2 (VMAT2) inhibitor indicated for the treatment of adults with chorea associated with Huntington's disease.*

CRITERIA FOR APPROVAL:

1. Patient must have a diagnosis of chorea associated with Huntington's Disease; **AND**

2. The request must come from the treating neurologist; AND

3. Patient must be at least 18 years of age; **AND**

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

5. The prescribed dose must be provided and within dosing recommendations per the manufacturer label; **AND**

~~5. All previous therapies must be documented. Unless contraindicated, the patient must have trialed and failed to find improvement in symptoms after at least a **60-day trial** of **amantadine**; **AND**~~

6. Patient must not be taking an MAOI (at least 14-days post-therapy), reserpine (must be >20 days post therapy) or any other concurrent VMAT 2 inhibitor.

Approval Duration:

Initial approval will be for 3 months.

Criteria for reauthorization:

1. Demonstrate continued documented compliance; **AND**
2. Documentation of positive clinical response and/or stabilization of symptoms must be provided

Continuation of therapy will be granted for 12 months.

Nuzyra

Nuzyra (omadacycline) is a tetracycline class antibacterial indicated in adults patients for the treatment of community-acquired bacterial pneumonia (CABP) and for the treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible microorganisms*

To reduce the development of drug-resistant bacteria and maintain the effectiveness of **NUZYRA** and other antibacterial drugs, **NUZYRA** should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria.

CRITERIA FOR APPROVAL:

1- Patient has a diagnosis of community acquired bacterial pneumonia (CABP) **OR** acute bacterial skin and skin structure infection (ABSSSI); **AND**

2- The patient is within the age range as recommended by the FDA label; **AND**

3- The patient has experienced an inadequate treatment response, intolerance, or contraindication to at least one preferred agent from each class of antibiotics used to treat the submitted diagnosis **AND** a trial of linezolid when appropriate **OR** the provider submits clinical rationale as to why these agents would not be appropriate for the patient including the bacteria are NOT susceptible to any other antibiotics (documentation of culture and sensitivity report must be provided).

4- Nuzyra may be authorized for patients who have initiated oral or intravenous therapy in a hospital facility and are discharged to an outpatient setting where the course of therapy will be completed.

Approval Duration:

Total treatment duration will not exceed 14 days per course.

***Pneumonia, community-acquired:** *Streptococcus pneumoniae*, *Staphylococcus aureus* (methicillin susceptible isolates), *Haemophilus influenzae*, *H. parainfluenzae*, *Klebsiella pneumoniae*, *Legionella pneumophila*, *Mycoplasma pneumoniae*, and *Chlamydophila pneumoniae*.

***Skin and skin structure infections:** Treatment of acute bacterial skin and skin structure infections (ABSSSI) in adult patients caused by susceptible *S. aureus* (methicillin-susceptible and -resistant isolates), *Staphylococcus lugdunensis*, *Streptococcus pyogenes*, *Streptococcus anginosus* grp. (includes *S. anginosus*, *S. intermedius*, and *S. constellatus*), *Enterococcus faecalis*, *Enterobacter cloacae*, and *K. pneumoniae*.

Invega Hafyera

*Invega Hafyera may only be authorized after four months' treatment with Invega Sustenna or at least a one three-month cycle with Invega Trinza.

ANTIPSYCHOTICS, ATYPICAL

CLASS PA CRITERIA: All antipsychotic agents require prior authorization for children up to eighteen (18) years of age. All PA requests for antipsychotics for children 6 years of age and younger will be reviewed by Medicaid's consultant psychiatrist.

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.

Patients shall be grandfathered onto their existing therapy, provided the requested agent is being used according to the manufacturer label. Continuation of therapy for an off-label indication or non-standard dosage may be granted a thirty (30) day prior-authorization while the Medical Director reviews the request.

SINGLE INGREDIENT		
ABILIFY MAINTENA (aripiprazole)[CL] aripiprazole tablets ARISTADA (aripiprazole)[CL] ARISTADA INITIO (aripiprazole)[CL] clozapine INVEGA ER (paliperidone) INVEGA HAFYERA (paliperidone) [CL] INVEGA SUSTENNA (paliperidone)[CL] INVEGA TRINZA (paliperidone)* [CL] LATUDA (lurasidone) olanzapine olanzapine ODT PERSERIS (risperidone)[CL] quetiapine ER quetiapine** AP for the 25 mg Tablet Only RISPERDAL CONSTA (risperidone)[CL] risperidone solution, tablet, ODT SAPHRIS (asenapine) ziprasidone	ABILIFY MYCITE (aripiprazole) ABILIFY TABLETS (aripiprazole) ADASUVE (loxapine) aripiprazole solution asenapine sublingual tablets CAPLYTA (lumateperone) clozapine ODT CLOZARIL (clozapine) FANAPT (iloperidone) GEODON (ziprasidone) GEODON IM (ziprasidone) LYBALVI (olanzapine and samidorphan) NUPLAZID (pimavanserin) *** olanzapine IM[CL] paliperidone ER REXULTI (brexipiprazole) RISPERDAL (risperidone) SECUADO (asenapine) SEROQUEL (quetiapine) SEROQUEL XR (quetiapine) VERSACLOZ (clozapine) VRAYLAR (capriprazine)**** VRAYLAR DOSE PAK (capriprazine)**** ZYPREXA (olanzapine)	**The following criteria exceptions apply to the specified products:** *Invega Trinza will be authorized after four months' treatment with Invega Sustenna Invega Hafyera may only be authorized after four months' treatment with Invega Sustenna or at least a one three-month cycle with Invega Trinza. **Quetiapine 25 mg will be authorized: 1. For a diagnosis of schizophrenia **or** 2. For a diagnosis of bipolar disorder **or** 3. When prescribed concurrently with other strengths of Seroquel in order to achieve therapeutic treatment levels. **Quetiapine 25 mg will not be authorized for use as a sedative hypnotic.** ***Nuplazid may only be authorized for the treatment of Parkinson Disease Induced Psychosis after documented treatment failure with quetiapine.

Ergot Alkaloids

"Other" category of antimigraine agents, acute

CAFERGOT (ergotamine/caffeine)
D.H.E 45 AMPULE (dihydroergotamine)
dihydroergotamine injection, nasal spray
MIGERGOT RECTAL SUPPOSITORY (ergotamine/caffeine)
MIGRANAL SPRAY (dihydroergotamine)
TRUDHESA SPRAY (dihydroergotamine)

*All non-preferred Ergot alkaloid agents require three (3) day trials of (2) preferred triptans as well as a three (3) day trial of a preferred triptan using the same route of administration as the requested agent (if available), before they will be approved, unless one (1) of the exceptions on the PA form is present.
Note: Ergot derivatives should not be used with or within 24 hours of triptans.

***Additional Ergot Alkaloid criteria:**

Nasal spray:
dihydroergotamine nasal spray and Trudhesa spray may only be authorized after a trial and failure of Migranal spray.

Rectal suppository:
Migerot rectal suppository may only be authorized after a trial and failure of a preferred triptan nasal spray.

Injection:
dihydroergotamine injection and D.H.E 45 ampule may only be approved for cluster headaches.

Lybalvi

Patient must have had a positive response with olanzapine and experienced clinically significant weight gain (documentation must be provided) which necessitated disruption of treatment. Patient must also have had an intolerance, inadequate treatment response or contraindication to 2 preferred antipsychotics (such as aripiprazole and ziprasidone) which have a lower potential of weight gain prior to Lybalvi approval. ***Prior to initiating Lybalvi, there should be at least a 7-day opioid-free interval from the last use of short-acting opioids, and at least a 14-day opioid-free interval from the last use of long-acting opioids to avoid precipitation of opioid withdrawal.***

ANTIPSYCHOTICS, ATYPICAL

CLASS PA CRITERIA: All antipsychotic agents require prior authorization for children up to eighteen (18) years of age. All PA requests for antipsychotics for children 6 years of age and younger will be reviewed by Medicaid's consultant psychiatrist.

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.

Patients shall be grandfathered onto their existing therapy, provided the requested agent is being used according to the manufacturer label. Continuation of therapy for an off-label indication or non-standard dosage may be granted a thirty (30) day prior-authorization while the Medical Director reviews the request.

SINGLE INGREDIENT

ABILIFY MAINTENA (aripiprazole)[CL]	ABILIFY MYCITE (aripiprazole)	**The following criteria exceptions apply to the specified products:**
aripiprazole tablets	ABILIFY TABLETS (aripiprazole)	
ARISTADA (aripiprazole)[CL]	ADASUVE (loxapine)	*Invega Trinza will be authorized after four months' treatment with Invega Sustenna
ARISTADA INITIO (aripiprazole)[CL]	aripiprazole solution	
clozapine	asenapine sublingual tablets	Invega Hafyera may only be authorized after four months' treatment with Invega Sustenna or at least a one three-month cycle with Invega Trinza.
INVEGA ER (paliperidone)	CAPLYTA (lumateperone)	
INVEGA HAFYERA (paliperidone) [CL]	clozapine ODT	Patient must have had a positive response with olanzapine and experienced clinically significant weight gain (documentation must be provided) which necessitated disruption of treatment. Patient must have also have had an intolerance, inadequate treatment response or contraindication to 2 preferred antipsychotics (such as aripiprazole and ziprasidone) which have a lower potential of weight gain prior to Lybalvi approval. ***Prior to initiating Lybalvi, there should be at least a 7-day opioid-free interval from the last use of short-acting opioids, and at least a 14-day opioid-free interval from the last use of long-acting opioids to avoid precipitation of opioid withdrawal.***
INVEGA SUSTENNA (paliperidone)[CL]	CLOZARIL (clozapine)	
INVEGA TRINZA (paliperidone)* [CL]	FANAPT (iloperidone)	
LATUDA (lurasidone)	GEODON (ziprasidone)	
olanzapine	GEODON IM (ziprasidone)	
olanzapine ODT	LYBALVI (olanzapine and samidorphan)	
PERSERIS (risperidone)[CL]	NUPLAZID (pimavanserin) ***	
quetiapine ER	olanzapine IM[CL]	
quetiapine** AP for the 25 mg Tablet Only	paliperidone ER	
RISPERDAL CONSTA (risperidone)[CL]	REXULTI (brexipiprazole)	
risperidone solution, tablet, ODT	RISPERDAL (risperidone)	
SAPHRIS (asenapine)	SECUADO (asenapine)	
ziprasidone	SEROQUEL (quetiapine)	
	SEROQUEL XR (quetiapine)	
	VERSACLOZ (clozapine)	
	VRAYLAR (cariprazine)****	
	VRAYLAR DOSE PAK (cariprazine)****	
	ZYPREXA (olanzapine)	
	ZYPREXA IM (olanzapine)[CL]	

Kerendia

Kerendia (finerenone) *is a nonsteroidal Mineralocorticoid (Aldosterone) Receptor Antagonists indicated to reduce the risk of sustained eGFR decline, end-stage kidney disease, cardiovascular death, nonfatal myocardial infarction, and hospitalization for heart failure in adult patients with chronic kidney disease associated with type 2 diabetes.*

CRITERIA FOR APPROVAL:

1. Patient has a diagnosis of chronic kidney disease associated with type 2 diabetes; **AND**

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

3. Prescribed by, or in consultation with, a cardiologist, endocrinologist, or nephrologist; **AND**

4. Prior to initiation of Kerendia, the patient meets ***ALL the following*****:**

   a) Estimated glomerular filtration rate ≥ 25 mL/min/1.73 m^2 and < 75 mL/min/1.73 m^2; and
   b) Urine albumin-to-creatinine ratio ≥ 30 mg/g; and
   c) Serum potassium level ≤ 5.0 mEq/L; **AND**

5. Patient is currently receiving a maximally tolerated angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) **PLUS** a preferred agent containing a sodium glucose transport protein 2 (SGLT2) inhibitor* that is indicated for use in patients with chronic kidney disease (such as canagliflozin and dapagliflozin) unless the patient has an intolerance or contraindication to these agents.

   *Exemption requests from this requirement (not including intolerance or contraindication) would require an appeal to the medical director providing medical reasoning as to why SGLT2 therapy is not appropriate for the patient.

Approval Duration:

Initial approval will be for 6 months.

Criteria for reauthorization:

1. Demonstrate continued documented compliance; **AND**

2. Documentation of positive clinical response and/or stabilization to therapy must be provided (such as stabilization of eGFR, lack of hospitalization due to renal or cardiovascular disease etc.)

Continuation of therapy will be granted for 12 months.

Analgesics, Narcotic Long-Acting- Fentanyl

Non-preferred agents require six (6) day trials of three (3) chemically distinct preferred agents (excluding fentanyl) **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.

Clinical PA on preferred fentanyl patches (used safely and appropriately- no step therapy required)

fentanyl transdermal 12, 25, 50, 75, 100 mcg/hr [CL]