HEALTH INFORMATION designs

Texas HHSC DUR Board Meeting

Prospective Prior Authorization Proposals

October 23, 2020

Summary of Proposed Clinical Prior Authorizations

New Business

- Evrysdi (risdiplam) oral solution
  - New criteria
- Calcitonin Gene-Related Peptide Receptor (CGRP) Antagonists, Acute
  - Nurtec (rimegepant)/Ubrelvy (ubrogepant)
  - New criteria
- Oriahnn (elagolix, estradiol and norethindrone) capsules
  - New criteria
- Vyvanse (lisdexamfetamine) capsules/chewable tablets
  - Criteria revision
- Wakix (pitolisant) tablets
  - New criteria
- Xywav (oxybate salts) oral solution
  - New criteria

These classes were recommended for review by the MCOs and the Vendor Drug Program to ensure appropriate and safe utilization.

Evrysdi (risdiplam)
Clinical Prior Authorization Proposal

Evrysdi (risdiplam) oral solution

- Evrysdi is an oral solution indicated for the treatment of spinal muscular atrophy (SMA) in patients 2 months of age and older
  - It is given daily
  - Dosage is based on weight; maximum daily dose is 5mg
- It comes as 0.75 mg/1 mL and the cost is approximately $13,400 per 80mL bottle[1]

**Costs shown do not include any rebates that may be available*

1. Evrysdi. In: Red Book Online. Greenwood Village (CO): Truven Health Analytics; 2020 [cited 2020 Oct 23]. Available from www.micromedexsolutions.com.

Guidelines for the management of Spinal Muscular Atrophy

- Treatment is recommended to be proactive – therapy should start as early as possible – nutrition and respiratory assistance should be provided
- Disease-modifying therapies for SMA are available: nusinersen and onasemnogene abeparvovec
- For infants and very young children with SMA who are not ventilator-dependent, disease-modifying therapy is recommended
- For children up to 12 years of age with moderate symptoms of SMA, treatment with nusinersen is recommended
- Treatment of older children, adults and patients with advanced SMA should be individualized; limited observational data suggest that older children and adults may benefit from nusinersen, but data is not available for onasemnogene abeparvovec in these populations

Michelson D, Ciafaloni E, Ashwal S, et al. Evidence in focus: Nusinersen use in spinal muscular atrophy: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. Neurology Nov 2018;91(20):923-933.

Glascock J, Sampson J, Haidet-Phillips A, et al. Treatment Algorithm for Infants Diagnosed with Spinal Muscular Atrophy through Newborn Screening. J Neuromusc Dis 2018;5(2):145-158.

Finkel RS, Mercuri, E, Meyer OH, et al. Diagnosis and management of spinal muscular atrophy: Part 2: Pulmonary and acute care; medications, supplements and immunizations; other organ systems; and ethics. Neuromuscular Disorders 2018;28:197-207.

Evrysdi oral solution Clinical PA Proposal

Approval Criteria:

- This will be a manual PA
- Initial PA request:
  - Prescribed by, or in consultation with, a neurologist or pediatrician specializing in the treatment of SMA
  - Diagnosis of SMA in the last 730 days (documentation of diagnosis and baseline motor function tests must be provided)
  - Client will not have concurrent therapy with nusinersen or onasemnogene abeparvovec and has not had prior therapy with onasemnogene abeparvovec
  - Client does not have advanced SMA (defined as ventilator dependence > 16 hours/day or tracheostomy)
  - Client has not been hospitalized for a pulmonary event in the last 60 days
  - Client has not had surgery for scoliosis in the last 365 days
  - Dose is ≤ 5mg/day
- Renewal request:
  - Client does not have advanced SMA
  - Client has had a positive response to treatment, demonstrated by clinical improvement or no decline in function (updated functional scores must be provided)

CGRP Antagonists, Acute
Clinical Prior Authorization Proposal

CGRP Antagonists, Acute

- Nurtec (rimegepant) and Ubrelvy (ubrogepant) are included in this edit proposal
- Indicated for the acute treatment of migraine with or without aura in adults
- Recommended dose:
  - Nurtec (rimegepant)
    - 75mg orally as needed
    - Maximum dose is 75mg/24 hours
    - Safety of treating more than 15 migraines in 30 days has not been established
    - Cost is approximately $1020 for 8 tablets[1]
  - Ubrelvy (ubrogepant)
    - 50-100mg orally as needed – second dose may be administered at least 2 hours after initial dose
    - Maximum dose is 200mg/24 hours
    - Safety of treating more than 8 migraines in 30 days has not been established
    - Cost is approximately $1020 for 10 tablets (for both 50mg and 100mg tablets)[2]

**Costs shown do not include any rebates that may be available*

1. Nurtec. In: Red Book Online. Greenwood Village (CO): Truven Health Analytics; 2020 [cited 2020 Oct 23]. Available from www.micromedexsolutions.com.

2. Ubrelvy. In: Red Book Online. Greenwood Village (CO): Truven Health Analytics; 2020 [cited 2020 Oct 23]. Available from www.micromedexsolutions.com.

Guidelines for the management of Acute Migraine

- Use NSAIDs, nonopioid analgesics, acetaminophen or caffeinated analgesic combinations for mild-to-moderate attacks
- Use migraine-specific agents (triptans) for moderate or severe attacks and mild-to moderate attacks that respond poorly to NSAIDs or caffeinated combinations
- Use nonoral formulations in patients whose attacks are associated with severe nausea or vomiting
- Avoid medication overuse – patients who use acute treatments for more than 2 headache days per week should be offered preventative treatment
- Patients who have contraindications to the use of triptans or who have failed to respond to or tolerate at least 2 oral triptans (as determined by an assessment tool, such as the Migraine Treatment Optimization Questionnaire [mTOQ]) or healthcare provider attestation are eligible for ubrogepant, rimegepant or a neuromodulation device

The American Headache Society position statement on integrating new migraine treatments into clinical practice. Headache: The Journal of Head and Face Pain 59.1 (2019): 1-18.

CGRP Antagonists, Acute Clinical PA Proposal

Approval Criteria:

- Prescribed by, or in consultation with, a neurologist, pain specialist or headache specialist [manual]
- Age ≥ 18 years
- Diagnosis of migraine headache in the last 730 days
- Initial request: trial of 2 different triptan agents in the last 180 days
- No diagnosis of severe hepatic impairment (rimegepant) or end stage renal disease (ubrogepant) found in the last 365 days
- No claim for a contraindicated drug found in the last 30 days
- Requested quantity does not exceed the recommended dose per month

Oriahnn (elagolix, estradiol and norethindrone) Clinical Prior Authorization Proposal

Oriahnn (elagolix, estradiol and norethindrone)

- Oriahnn is a combination of elagolix, estradiol and norethindrone
- It is approved for use in patients with heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women
- Recommended dose is 1 capsule twice a day for up to 24 months
- Use should be limited to 24 months due to the risk of continued bone loss, which may not be reversible
- Cost is approximately $1089 for a 28 days supply[1]

**Costs shown do not include any rebates that may be available*

1. Oriahnn. In: Red Book Online. Greenwood Village (CO): Truven Health Analytics; 2020 [cited 2020 Oct 23]. Available from www.micromedexsolutions.com

Guidelines for the Treatment of Uterine Fibroids

UpToDate (2020)

- In patients who do not desire future fertility, first-tier treatment includes hysteroscopic fibroid resection or medical treatment aimed at reducing heavy menstrual bleeding (HMB)
  - Initial recommended medical treatment is combined estrogen-progestin contraceptive (pills, patch or ring)
- For patients whose symptoms persist despite a trial of one or more first-tier therapies, second tier medical treatments include gonadotropin-releasing hormone (GnRH) agonists and antagonists. Uterine artery embolization (UAE) is also a treatment option
- Third-tier treatments include focused ultrasound surgery and, in rare cases, endometrial ablation
- In patients who desire fertility, myomectomy is typically the first option. Most medical therapies are not used because they preclude conception

Stewart EA. Uterine fibroids (leiomyomas): Treatment Overview. In: UpToDate, Barbieri RL (Ed), UpToDate, Waltham, MA, 2020.

Oriahnn Clinical PA Proposal

Approval Criteria:

- Client is ≥ 18 years of age
- Diagnosis of uterine leiomyoma found in the last 730 days
- Claim for an NSAID and an oral contraceptive in the last 180 days
- No diagnosis of osteoporosis or hepatic impairment found in the last 365 days
- No claim for a contraindicated medication found in the last 90 days
- No history of thromboembolic disorder found in the last 730 days
- If the client is greater than 35 years of age, not a current smoker
- No history of uncontrolled hypertension found in the last 180 days [manual]
- No history of suicide attempt in the last 365 days
- No history of breast cancer or other hormonally sensitive cancer in the last 365 days
- Client does not exceed 2 capsules daily AND does not exceed total therapy duration of 24 months

Vyvanse (lisdexamfetamine) Clinical Prior Authorization Revision Proposal

Vyvanse (lisdexamfetamine)

- Vyvanse is indicated for:
  - Treatment of ADHD in patients aged 6 and older
  - Treatment of moderate to severe binge eating disorder (BED) in adults
- Clinical prior authorization currently in place for clients with ADHD, presenting criteria today for clients with BED
- Dosing for BED:
  - Recommended dose is 50mg to 70mg per day
  - Maximum dose is 70mg per day
- Cost is approximately $12.76 per capsule/tablet, regardless of strength ($383 for 30 days supply)[1]

**Costs shown do not include any rebates that may be available*

1. Vyvanse. In: Red Book Online. Greenwood Village (CO): Truven Health Analytics; 2020 [cited 2020 Oct 23]. Available from www.micromedexsolutions.com

Guidelines for the treatment of Binge Eating Disorder

- Psychotherapy (cognitive behavior therapy [CBT], interpersonal psychotherapy and dialectical behavior therapy) rather than behavioral weight loss therapy or pharmacotherapy is recommended
- For patients with BED who do not have access to psychotherapy, decline it or do not respond to it, pharmacotherapy with an SSRI, topiramate, zonisamide or lisdexamfetamine is a reasonable alternative

Yager J, Devlin MJ, Halmi KA, et al. Guideline Watch (August 2012): Practice Guideline for the Treatment of Patients with Eating Disorders, 3rd Edition. American Psychiatric Association (APA) Practice Guidelines.

Lock J, La Via MC. The American Academy of Child and Adolescent Psychiatry (AACAP) Committee on Quality Issues (CQI). Practice Parameter for the Assessment and Treatment of Children and Adolescents with Eating Disorders. J Am Acad Child Adolesc Psychiatry 2015;54(5):412-425.

Binge Eating Disorder

TX Medicaid BED Data* Calendar Year 2019	
Number of unique clients with a diagnosis of BED	208
Of those clients with a diagnosis of BED, number that had at least 1 claim for Vyvanse in CY 2019	21

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Vyvanse Clinical Prior Authorization Proposal for BED

Approval Criteria:

- Diagnosis of BED found in the last 730 days
- Client is ≥ 18 years of age
- At least 60 days therapy with another agent for the treatment of BED in the last 180 days
- No diagnosis of substance abuse found in the last 365 days
- Concurrent therapy with another extended release stimulant not found in the last 14 days
- Diagnosis of severe cardiac disease not found in the last 365 days
- Claim for a monoamine oxidase (MAO) inhibitor not found in the last 14 days
- Dose does not exceed maximum recommended

Wakix (pitolisant)
Clinical Prior Authorization Proposal

Wakix (pitolisant)

- Wakix is a histamine-3 (H3) receptor antagonist indicated for the treatment of excessive daytime sleepiness (EDS) in adult patients with narcolepsy
- Maximum recommended dose is 35.6mg daily
- Cost is approximately $13,644 for 30 days supply at a dose of 35.6mg daily[1]
- Cost is approximately $6822 for 30 days supply at a dose of 17.8mg daily[1]

**Costs shown do not include any rebates that may be available*

1. Wakix. In: Red Book Online. Greenwood Village (CO): Truven Health Analytics; 2020 [cited 2020 Oct 23]. Available from www.micromedexsolutions.com

Guidelines for the treatment of EDS associated with narcolepsy

- Treatment should alleviate daytime sleepiness in order to optimize patients' daily functioning at work, school, home and personal life
- Treatment options:
  - Modafinil and armodafinil have been shown to be effective for the treatment of EDS in patients with narcolepsy (Level 1)
  - Sodium oxybate is effective for treatment of cataplexy, daytime sleepiness and disrupted sleep due to narcolepsy (Level 1)
  - Amphetamine, methamphetamine, dextroamphetamine and methylphenidate are effective for treatment of daytime sleepiness due to narcolepsy (Level 2)

Krahn LE, Hershner S, Loeding LD, et al. Quality measures for the care of patients with narcolepsy. J Clin Sleep Med 2015;11(3):335-355.

Wakix Clinical Prior Authorization Proposal

Approval Criteria:

- Client is ≥ 18 years of age
- Diagnosis of narcolepsy found in the last 730 days
- At least 30 days therapy with modafinil or armodafinil found in the last 90 days
- No diagnosis of end stage renal disease found in the last 365 days
- If the client has a diagnosis of hepatic impairment or moderate to severe renal impairment, dose is ≤ 17.8mg daily; if no diagnoses are found, the dose is ≤ 35.6 mg daily
- Medication is being prescribed by, or in consultation with, a specialist (psychiatrist, neurologist, sleep specialist) [manual]

Xywav (oxybate salts)
Clinical Prior Authorization Proposal

Xywav (oxybate salts)

- Xywav (calcium, magnesium, potassium and sodium oxybates) oral solution is indicated for the treatment of cataplexy or excessive daytime sleepiness (EDS) in patients 7 years of age and older with narcolepsy
- Recommended dosage range: 6 to 9 grams per night, divided into 2 doses
- The active moiety of Xywav is oxybate or gamma-hydroxybutyrate (GHB) – it is a schedule 3 controlled substance
- Xywav is only available through a REMS program
- Lower sodium content than Xyrem, which carries warnings for sodium content
- Cost is not currently available

Xyrem Utilization

TX Medicaid Xyrem Utilization Data* Calendar Year 2019	
Number of claims	225
Unique number of clients	44
Total cost**	$2,688,852
Unique number of clients with a diagnosis of hypernatemia	0
Unique number of clients with a diagnosis of hypertension	9
Number of claims (clients with hypertension)	40
Total cost of claims (clients with hypertension)**	$580,599

**Includes both FFS and MCO data*

***Costs displayed do not contain any rebates that may be applied*

Guidelines for the treatment of cataplexy

- Treatment should alleviate daytime sleepiness in order to optimize patients' daily functioning at work, school, home and personal life
- Treatment options:
  - Sodium oxybate is effective for treatment of cataplexy, daytime sleepiness and disrupted sleep due to narcolepsy (Level 1)
  - Tricyclic antidepressants, SSRIs and venlafaxine may be effective treatment for cataplexy (Level 2)

Krahn LE, Hershner S, Loeding LD, et al. Quality measures for the care of patients with narcolepsy. J Clin Sleep Med 2015;11(3):335-355.

Xywav Clinical Prior Authorization Proposal

Approval Criteria:

- Medication is prescribed by, or in consultation with, a neurologist or sleep specialist
- Client is ≥ 7 years of age
- Diagnosis of alcohol or substance abuse not found in the last 730 days
- No active claim for a CNS depressant agent found
- Requested dose is ≤ 9 grams per day
- Diagnosis of narcolepsy or cataplexy found in the last 730 days

Questions?