Agenda Item: 3

ProDUR Quantity Limits
Select CNS Stimulants
Impact

The DUR Commission reviewed quantity limits for stimulants used in the treatment of Attention Deficit Hyperactivity Disorder (ADHD) and Narcolepsy at the February 2015 meeting. The DUR made recommendations to change or add quantity limits on select CNS stimulants (Table 1). At the request of the DUR, the proposed quantity limits were sent to the medical and pharmacy associations for their comment (any written comment received are included in the public comment section of the meeting materials). Additionally, the DUR requested claims exceeding the proposed quantity limits be identified to determine the impact to members, providers, and the prior authorization department.

Table 1. Impact of Proposed Quantity Limits on Select CNS Stimulants
January 2015 claims

Drug (applies to brand and generic)	**Proposed QL**	**N of Claims** (age 0-20 years	**N of Claims** (age 21+ years)	**Current QL**
Adderall IR 12.5mg	90	2	0	120
Adderall IR 20mg	90	10	22	120
Concerta 18mg	30	21	0	60
Concerta 27mg	30	12	0	60
Concerta 54mg	30	115	7	60
Focalin IR 2.5mg	60	6	1	None
Focalin IR 5mg	60	50	1	None
Focalin IR 10mg	60	75	2	None
Focalin XR 5mg	30	16	0	60
Focalin XR 10mg	30	35	0	60
Focalin XR 15mg	30	34	0	90
Focalin XR 20mg	30	63	0	60
Focalin XR 25mg	30	30	0	60
Focalin XR 30mg	30	79	0	60
Ritalin IR 5mg	90	44	0	None
Ritalin IR 10mg	90	62	20	None
Ritalin IR 20mg	90	24	19	None

IR = immediate-release; N = number; QL = quantity limit; XR = extended-release

Total number of unique members: 751
Total number of unique prescribers: 305
Number of unique prescribers with ≥ 2 claims in January 2015: 123
Number of unique prescribers with ≥ 3 claims in January 2015: 67

CNS Stimulants and Atomoxetine
(f.k.a. ADHD/ADD/Narcolepsy Agents)

In January 2015, Vyvanse received FDA approval for the treatment of moderate to severe Binge Eating Disorder (BED). The DSM-5 included BED as a formal eating disorder diagnosis. The DSM-5 diagnosis requires the following:

- Episodes of binge eating, defined as consuming an amount of food in a discrete period of time (e.g., two hours) that is definitely larger than what most people would eat in a similar amount of time under similar circumstances. During episodes, patients feel they lack control over eating (e.g., patients feel they cannot stop eating or control the amount or what they are eating).
- Binge eating episodes are marked by at least three of the following:
    - Eating more rapidly than normal
    - Eating until feeling uncomfortably full
    - Eating large amounts of food when not feeling physically hungry
    - Eating alone because of embarrassment by the amount of food consumed
    - Feeling disgusted with oneself, depressed, or guilty after overeating
- Episodes occur, on average, at least once a week for three months
- No regular use of inappropriate compensatory behaviors (e.g., purging, fasting, or excessive exercise) as are seen in bulimia nervosa
- Binge eating does not occur solely during the course of bulimia nervosa or anorexia nervosa

It is estimated the lifetime prevalence in the United States of BED in women and men is 3.5% and 2.0% respectively. In addition, BED is associated with numerous psychiatric and nonpsychiatric disorders. Psychotherapy, behavioral weight loss therapy, and pharmacotherapy have been used to treat BED. Patients should be evaluated in order to plan treatment. The evaluation should include the following:

- Psychiatric status – history and mental status exam should include attitude toward body weight and shape; self-esteem; and comorbid psychiatric disorders.
- Medical Status – history and physical exam should focus on parameters and comorbidities associated with excess weight or obesity in appropriate patients.
- Nutritional status – history should include lifetime weight and dieting history; current eating patterns; types of overeating; frequency and intensity of binge eating episodes; and physical activity and exercise patters.

Psychotherapy is recommended as first-line treatment of BED. Cognitive behavior therapy (CBT) has been the most studied and is recommended over other psychotherapies. Pharmacotherapy can be used as a second-line treatment but its efficacy is usually less than that of psychotherapy. Several medications have been studied, including serotonin reuptake inhibitors (SSRIs; such as citalopram, escitalopram, fluoxetine, fluvoxamine, and sertraline), antiepileptic drugs (such as topiramate and zonisamide), and medications indicated for attention deficit hyperactivity disorder (ADHD; such as atomazetine and lisdexamfetamine). Fluvoxamine and

topiramate carry compendia indications, while lisdexamfetamine carries an FDA indication for the treatment of BED.

Given the updated indication for Vyvanse, an update of prior authorization criteria is required. Additionally, criteria for treatment of ADD/ADHD/Narcolepsy is being strengthened to require a check of the Iowa Prescription Monitoring Program as a part of the PA process due to the potential for abuse or dependence with CNS stimulants.

Current Prior Authorization Criteria

Prior authorization (PA) is required for ADD/ADHD/Narcolepsy agents for patients 21 years of age or older under the following conditions:

1. Attention Deficit Disorder (ADD) or Attention Deficit Hyperactivity Disorder (ADHD) meeting the DSM-IV criteria and confirmed by a standardized rating scale (such as Conners, Vanderbilt, Brown, SNAP-IV). Symptoms must have been present before twelve (12) years of age and there must be clear evidence of clinically significant impairment in two or more environments (social, academic, or occupational).
2. Narcolepsy with diagnosis confirmed with a recent sleep study (ESS, MSLT, PSG).
3. Excessive sleepiness from obstructive sleep apnea/hypopnea syndrome (OSAHS) with documentation of non-pharmacological therapies tried (weight loss, position therapy, CPAP at maximum titration, BiPAP at maximum titration or surgery) and results from a recent sleep study (ESS, MSLT, PSG) with the diagnosis confirmed by a sleep specialist.

Payment for a non-preferred agent will be authorized only for cases in which there is documentation of a previous trial and therapy failure with a preferred agent. *If a non-preferred long-acting medication is requested, a trial of the preferred immediate release and extended release product of the same chemical entity is required.
The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

Proposed Prior Authorization Criteria

Prior authorization (PA) is required for ~~ADD/ADHD/Narcolepsy~~ CNS stimulants and Atomoxetine for patients 21 years of age or older. Prior to requesting prior authorization for any covered diagnosis, the prescriber must review the patient's use of controlled substances on the Iowa Prescription Monitoring Program website at https://pmp.iowa.gov/IAPMPWebCenter/. Payment for CNS stimulants and Atomoxetine will be considered under the following conditions:

1. Attention Deficit Disorder (ADD) or Attention Deficit Hyperactivity Disorder (ADHD) meeting the DSM-5 ~~IV~~ criteria and confirmed by a standardized rating scale (such as Conners, Vanderbilt, Brown, SNAP-IV). Symptoms must have been present before twelve (12) years of age and there must be clear evidence of clinically significant impairment in two or more current environments (social, academic, or occupational). Documentation of a recent clinical visit that confirms

the patient continues to require medication to treat the symptoms of ADD/ADHD will be required for renewals or patients newly eligible that are established on medication to treat ADD/ADHD.

2. Narcolepsy with diagnosis confirmed with a recent sleep study (ESS, MSLT, PSG).
3. Excessive sleepiness from obstructive sleep apnea/hypopnea syndrome (OSAHS) with documentation of non-pharmacological therapies tried (weight loss, position therapy, CPAP at maximum titration, BiPAP at maximum titration or surgery) and results from a recent sleep study (ESS, MSLT, PSG) with the diagnosis confirmed by a sleep specialist.
4. Binge Eating Disorder (Vyvanse only)
    - Patient is 18 to 55 years of age; and
    - Patient meets the DSM-5 criteria for Binge Eating Disorder; and
    - Patient has documentation of moderate to severe BED, as defined by the number of binge eating episodes per week (number of episodes must be reported); and
    - Patient has documentation of non-pharmacologic therapies tried, such as cognitive-behavioral therapy or interpersonal therapy, for a recent 3 month period, that did not significantly reduce the number of binge eating episodes; and
    - Patient has documentation of an adequate trial and therapy failure at a therapeutic dose with topiramate and fluvoxamine
    - Prescription is written by a psychiatrist or psychiatric nurse practitioner; and
    - Patient has a BMI of 25 to 45; and
    - Patient does not have personal or family history of cardiovascular disease; and
    - Patient has no history of substance abuse; and
    - Is not being prescribed for the treatment of obesity or weight loss; and
    - Doses above 70mg per day will not be considered.
    - Initial requests will be approved for 12 weeks.
    - Requests for renewal must include documentation of a change from baseline at week 12 in the number of binge days per week.

    DSM-5 Criteria

    i. Recurrent episodes of binge eating, including eating an abnormally large amount of food in a discrete period of time and has a feeling of lack of control over eating; and
    ii. The binge eating episodes are marked by at least three of the following:
        1. Eating more rapidly than normal
        2. Eating until feeling uncomfortably full
        3. Eating large amounts of food when not feeling physically hungry
        4. Eating alone because of embarrassment by the amount of food consumed

5. Feeling disgusted with oneself, depressed, or guilty after overeating; and

iii. Episodes occur at least 1 day a week for at least 3 months; and

iv. No regular use of inappropriate compensatory behaviors (e.g. purging, fasting, or excessive exercise) as are seen in bulimia nervosa; and

v. Does not occur solely during the course of bulimia nervosa or anorexia nervosa.

Moderate to Severe BED

Based on the number of binge eating episodes per week:

Moderate - 4 to 7

Severe – 8 to 13

Extreme – 14 or more

Payment for a non-preferred agent will be authorized only for cases in which there is documentation of a previous trial and therapy failure with a preferred agent. *If a non-preferred long-acting medication is requested, a trial ~~of~~ with the preferred immediate release and extended release product of the same chemical entity (methylphenidate class) or chemically related agent (amphetamine class) is required.

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.