Obesity Action Coalition

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02/27/2024

Drug Use Research & Management Program
Oregon State University
500 Summer Street NE, E35
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RE: Drug Effectiveness Review Project Summary Report – Pharmacologic Agents for Weight Management

The Obesity Action Coalition (OAC) appreciates the opportunity to comment on the Oregon State University drug effectiveness review of medications for weight management. The OAC is a national non-profit organization dedicated to giving a voice to individuals affected by the disease of obesity. We are pleased OSU is giving obesity serious consideration and review to improve evidence-based care, which should include coverage for intensive behavioral therapy, metabolic/bariatric surgery, and FDA-approved anti-obesity medications.

The OAC proudly serves about 1,000 members living in Oregon and backed by more than 85,000 members across the United States. We applaud this legislation, as it improves access to obesity care and updates state policies into alignment with advances in science and clinical standards. Throughout the past decades, the prevalence of obesity has skyrocketed across our country and in Oregon – with 31 percent of adults and more than 14.5 percent of children (ages 10- 17) in the state currently affected by obesity.

There are multiple evidence-based treatments for people with obesity that mitigate the impacts of the disease and improve health outcomes. Unfortunately, the present landscape of obesity treatment coverage remains piecemeal and laden with arbitrary hurdles to receive comprehensive care. We applaud Oregon for moving to eliminate barriers to care – both for the long term and immediate health of those affected by obesity.

Since 2013, when the American Medical Association adopted formal policy declaring obesity as a complex and chronic disease and supporting patient access to the full continuum of evidence based obesity care, numerous federal and state policy organizations have echoed the AMA's position. These include the National Council of Insurance Legislators, National Lieutenant Governors Association, National Hispanic Caucus of State Legislators, and the National Black Caucus of State Legislators, and the Federal Office of Personnel Management.

Further, the American Academy of Pediatrics (AAP) released their evidence-based recommendations on medical care for those age 2 and older as part of its new "Clinical Practice Guideline (CPG) for the Evaluation and Treatment of Children and Adolescents with Obesity." The AAP guidelines contain key action statements, which represent evidence-based recommendations for evaluating and treating children with overweight and obesity and related health concerns. These recommendations include motivational interviewing, intensive health behavior and lifestyle treatment, pharmacotherapy and metabolic and bariatric surgery. The approach considers the child's health status, family system, community context, and resources. The comprehensive evidence-based

recommendations included in the CPG reflect just how far the understanding and care of childhood obesity has come and Oregon should be applauded for its forward thinking on obesity care – especially for those most in need.

Obesity is a complex chronic disease that extends beyond individual lifestyle choices to encompass a broader landscape of social determinants and systemic factors, contributing significantly to health inequities. Disparities in obesity rates are often closely intertwined with socioeconomic status, geographic location, and access to resources. Individuals in marginalized communities may face barriers to affordable and nutritious food options, safe spaces for physical activity, and unequal access to qualified providers of quality healthcare. These structural inequities exacerbate the prevalence of obesity among vulnerable populations, leading to a cycle of poor health outcomes. Tackling obesity requires a comprehensive approach.

Our country must acknowledge obesity for the chronic disease that it is and take steps to treat it in the same serious fashion as other chronic disease states such as diabetes and hypertension. As a voice for people living with obesity, OAC looks forward to working with the state of Oregon to ensure Medicaid recipients access to comprehensive obesity care for this complex and chronic disease.

We would be happy to meet and share further information and perspectives of people living with obesity. Should you have questions or need additional information, please reach out to our Policy Advisor, Chris Gallagher at chris@potomaccurrents.com. Thank you.

Sincerely,

Joseph Nadglowski, Jr.
OAC President and CEO

American Diabetes Association.
Connected for Life

Thank you for the opportunity to comment on the OSU drug effectiveness review of medications for weight loss. The American Diabetes Association (ADA) strongly supports providing comprehensive access to the evidence-based interventions to treat and manage the chronic disease of obesity in accordance with ADA's clinical Standards of Care. These interventions include intensive lifestyle modification counseling, anti-obesity medications and bariatric/metabolic surgery as recommended by a health professional.

Obesity is a complex, multifactorial, common, serious, relapsing, and costly chronic disease that serves as a major risk factor for developing conditions such as heart disease, stroke, type 2 diabetes, renal disease, non-alcoholic steatohepatitis, and 12 types of cancer (which make up 40 percent of all cancer diagnoses)[1]. Additionally, obesity contributes to many chronic and costly conditions including sleep apnea and increases the rate of physical injury including falls and sprains by 48 percent.[2]

ADA's 2023 Standards of Care reviewed the evidence and demonstrate that obesity management can delay the progression from prediabetes to type 2. Additionally, with greater than 10 percent BMI reduction other significant health benefits can be achieved. The 2024 American Diabetes Association *Standards of Care* recommends nutrition, physical activity, and behavioral therapy to achieve and maintain ≥5% weight loss for people with type 2 diabetes and overweight and obesity. In addition the ADA *Standards of Care* recommend that interventions should include high frequency greater than or equal to 16 sessions in 6 months with a focus on nutrition, physical activity, and behavioral strategies to achieve a 500-750 kcal/day energy deficit which have shown to be beneficial for weight loss and be considered when available. Treatment should be individualized to a person's preference and needs.[3]

For people with obesity, per-patient-per-year health care expenditures are estimated to be $4,217 greater than in those without obesity. As BMI decreases from 20% to 5% health expenditures for comorbid
conditions also decrease including diabetes, hypertension, arthritis, mental health issues among other conditions.[4] A study found that a per patient per month (PPPM) all-cause health care costs were reduced by $193.54 with >10% to ≤20% weight loss. The major drivers of cost savings were inpatient and outpatient costs.[15]

The Veteran's Administration (VA) created MOVE!, an intensive lifestyle modification program, that provides nutritional counseling, physical activity, and behavioral change support along with anti-obesity medication and bariatric/metabolic surgery. When MOVE! Is combined with anti-obesity medication treatment there was a $1,893 reduction in medical costs per veteran, greater weight management, and improved clinical health benefits than MOVE! alone. The reduction in medical costs resulted from less inpatient and emergency department utilization. The study provides evidence that support adding Medicaid coverage for treatment of obesity and overweight.[5]

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[1] Centers for Disease Control and Prevention. https://www.cdc.gov/cancer/obesity/index. Accessed April 26, 2023
[2] Finkelstein EA, Chen H, Prabhu M, Trogdon JG, Corso PS. The relationship between obesity and injuries among U.S. adults. Am J Health Promot. 2007 May-Jun;21(5):460-8. doi: 10.4278/0890-1171-21.5.460. PMID: 17515011.
[3] https://diabetesjournals.org/care/article/47/Supplement_1/S145/153942/8-Obesity-and-Weight-Management-for-the-Prevention
[4] Kenneth E. Thorpe, Curtis S. Florence, David H. Howard, Peter Joski, The Impact of Obesity On Rising Medical Spending, HEALTH AFFAIRS VOL. 23, NO. SUPPL1. https://www.healthaffairs.org/doi/epdf/10.1377/hlthaff.W4.480
[5] Source: Clinical and Cost Benefits of Anti-Obesity Medication for US Veterans Participating in the MOVE! Weight Management Program. W. Timothy Garvey, Mu Cheng, Abhilasha Ramasamy, B. Gabriel Smolarz, Suna Park, Neela Kumar, Nina Kim, Maral

The American Diabetes Association *Standards of Care* recommend pharmacotherapy be considered for people with diabetes and overweight or obesity along with lifestyle changes.[6] We strongly urge the Oregon Health Authority to consider adding coverage for a comprehensive benefit for obesity in line with current evidence-based standards of care. Medical intervention is effective in treating the chronic disease of obesity but unfortunately many people lack access to treatment. The American Diabetes Association supports adding Medicaid coverage in Oregon for person-centered intervention across the care continuum. Thank you for the opportunity to comment on the draft documents and urge the Oregon Health Authority to move forward with adding coverage of anti-obesity medication in conjunction with intensive behavioral therapies and bariatric/metabolic surgeries.

[6] https://diabetesjournals.org/care/article/47/Supplement_1/S145/153942/8-Obesity-and-Weight-Management-for-the-Prevention

Dear OHP,

Thank you for the opportunity to comment on adding FDA approved anti-obesity medications (AOM) as a covered benefit to Oregon Medicaid. I am in support of this proposal.

I am a family nurse practitioner. I have worked in the specialty of obesity medicine and bariatric surgery for 16.5 years at Southern Oregon Bariatric Center (SOBC) in Medford, Oregon. At SOBC we care for many Oregon Medicaid recipients who are affected by the disease of obesity. We provide robust education and care in nutrition, physical activity, and behavior modifications to support both weight loss and weight loss maintenance. When appropriate, we include bariatric surgery as a powerful part of our treatment plan. Additionally, we would use AOM's when indicated. Unfortunately, a significant limiting factor in our ability to fully utilize all of the FDA approved AOM's with our Oregon Medicaid population is the fact these medications are not covered by their plan. The out of pocket price for these medications are too cost prohibitive for the vast majority of our Oregon Medicaid recipients. Therefore, we are often left to treat our patient's disease of obesity without the full scope of proven therapies at our disposal.
Obesity is not only a chronic disease, but it is also progressive. As such, treatment must be comprehensive and life long, like management of any chronic disease. Including FDA approved AOM's for Oregon Medicaid recipients would give our patients a robust fighting chance at turning the tides of their disease of obesity from progressive and worsening to a state of active remission with all the benefits inherent therein.

Thank you for your consideration.

Sincerely,
Reeger Cortell, MSN, FNP-C, RNFA, WOCN, BFA
She/Her
Clinical Director
Southern Oregon Bariatric Center
537A Murphy Rd
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Hello,
My name is Erika La Vella, I am a bariatric surgeon practicing in Corvallis, OR at Samaritan Weight Management Institute. Weight loss medications play a important role in management of obesity before, after, and for those who are not good surgical candidates. In my clinic we offer comprehensive obesity management with collaboration with a clinical bariatrician and obesity medicine certified endocrinologist.

Often we have candidates for bariatric surgery who prove weight loss resistant while partaking in our comprehensive diet and lifestyle program. We consult with our bariatrician and use weight loss medications to help lose weight, improve mobility and become better surgical candidates.

After bariatric surgery, weight regain is a common phenomenon affecting upwards of 30% of patients within 5 years of surgery, having weight loss medications available and started early in the weight experience is essential to prevent co-morbidities from recurring in conjunction with our comprehensive diet and lifestyle program. There are no operations that treat weight regain without significant medical and surgical risks (malnutrition, failure to lose weight regardless of reoperation, increased risk of complications from previous surgical scaring).

I fully endorse the broadening of weight loss medications in this patient population as an adjunct for comprehensive obesity management.

Erika La Vella, DO, FASMBS
Medical Director
Samaritan Weight Management Institute
Corvallis, OR

To whom it may concern,

Thank you for including medications for obesity in your draft policy.

As Chair of the Access to Care Committee for the American Society of Metabolic and Bariatric Surgeons, we are writing to express our support in adding this benefit to your plan.

Obesity has been recognized by numerous medical associations including the American Medical Association as a chronic disease, and treatment options such as medications and metabolic surgery are vital for patients suffering from obesity. The current draft is a great step forward in offering better treatment options to patients in Oregon.

Thank you,

L. Renee Hilton, MD, FACS, FASMBS, DABS-FPDMBS
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March 20, 2024

Oregon P & T Committee

Re: Public Testimony for Teleconference on Drugs for Weight Management DERP Summary

Dear Committee Members,

I am providing written testimony regarding the DERP summary of drugs used for weight management (published 2024). I am a practicing physician in the Portland area with current ABIM board certification in Internal Medicine and Endocrinology as well as Obesity Medicine. I conduct NIH research into the physiology of weight regulation and the consequences of developing overweight and obesity. As part of my clinical practice, I have been prescribing drugs for weight management for 25 years.

First, thank you for your timely review. Becoming overweight and then developing obesity affects up to 80% of the US population (including Oregon) and adversely impacts over 200 different medical conditions. Having effective tools such as the FDA-approved anti-obesity medications covered in this review is critical to reducing the burden of these co-morbidities, especially for older Americans and those most vulnerable to health care inequities (e.g., lower socio-economic classes, from Black and Hispanic groups), groups in whom obesity rates are the highest.

I would like to comment on the following items:

Plain Language Summary:

1. As recently stated in the Joint Internation Consensus Statement For Ending Stigma of Obesity,[1] 0besity is a recognized chronic disease by the WHO, AMA, NIH, FDA, IRA, and the US Federal Government. Treatment for the disease of obesity should be consistent with treatment of other recognized chronic diseases in which lifestyle plays a significant role, including diabetes, hypertension, and hyperlipidemia. As such, while the opening statement “Medicines can help people lose weight” is technically true, when we use these drugs, we are not just treating a weight—we are treating a chronic disease and its complications. A more accurate statement would be that “Medications are used to treat the disease of obesity.”
2. As such, it is now considered customary in all published references to the disease of obesity to use person-first language, such as “patients with overweight or obesity” rather than “overweight patients” or “obese patients” or “patients who are obese.” This is similar to how we now refer to patients “with diabetes” rather than as “diabetics.”
3. Mention should also be made of palpitations, anxiety, tingling, and mood changes, common side effects in the FDA-approved combination of phentermine and topiramate.
4. The statement from the American Academy of Pediatrics (not American Pediatric Association) reads, “Pediatricians and other health care providers

should offer adolescents 12 years and older with obesity weight loss pharmacotherapy, according to medication indications, risks, and benefits, as an adjunct to intensive behavioral lifestyle therapy."[2] The use of the stronger "should" in children with obesity (not overweight) rather than "may" was intentional to prompt pediatric providers to deliver the best, evidence-based care.

5. The statement on Semaglutide studies presents data in an unconventional way and contains several inaccuracies. Normally, MACE (major adverse cardiovascular events) is a composite outcome encompassing death from cardiovascular causes, nonfatal myocardial infarction, and nonfatal stroke (3-point MACE), not just CV deaths as stated. Such a 3-point MACE was the primary outcome of the SELECT[3] trial referred to here. Also, it is customary to present both absolute and relative differences. A more accurate statement would be, "Semaglutide studies show that cardiovascular events (such as having a heart attack or stroke, or dying from one of these) were reduced in relative terms by 20% (2.5% (not 1.5%) in absolute terms) in treated people with overweight and obesity and vascular disease compared to placebo."
6. For the committee's perspective, what is left out is that this same study showed a 19% reduction (Hazards Ratio: 0.81, 95% CI 0.71-0.93) in total mortality. This is important for safety outcomes because it is not just "safe" to use (no worsening of total mortality), it actually reduces a patient's likelihood of dying from any cause, a significant milestone for this class of drugs akin to simvastatin in 1994 showing for the first-time reductions in CV and total mortality when used to treat patients with hypercholesterolemia.

Conclusions:

1. The information under the second bullet for the Weight Loss heading regarding exenatide (which causes a small amount of weight loss) and glyburide (which causes a small amount of weight gain, on average) applies to the treatment of diabetes, not obesity, and is not applicable to this review.
2. In this same heading (Weight Loss), any data on semaglutide's benefits on weight loss in those with obesity and with[4] and without diabetes[5] appear to have been left out, including similar superiority over intensive lifestyle behavior weight loss[6] as tirzepatide.[7] In fact, weight loss from both semaglutide and tirzepatide alone was two-fold or greater compared to intensive lifestyle behavior alone, with a non-clinically meaningful added benefit of less than 2% total weight loss (on total weight losses of 15% to 20% to drug alone) when drug therapy was combined with intensive lifestyle management.
3. It is important to not lump all weight loss drugs together when summarizing outcomes. For example, CV risk factors improve with increased weight loss. Changes in these variables using the GLP-1RA class are both significant and clinically meaningful as evidenced by RCT trials showing significant reductions in progression to type 2 diabetes,[8] CV outcomes and total mortality,[3] and heart failure.[9,10]

4. Under the safety bullet, data from the SELECT trial for semaglutide shows superior weight loss compared to placebo for out to 4 years[3] (not just 2 years) of continuous treatment.
5. The final statement in this section contains several inaccuracies or misleading statements. Every RCT published to date that includes a re-randomization phase after at least 1 year of therapy, including semaglutide[11] and tirzepatide[7] trials, shows weight regain upon re-assignment to placebo, demonstrating both the chronic nature of the disease of obesity and need for long-term, continuous medical therapy. In addition, the SELECT and STEP trials shows sustained reductions in weight, CV outcomes, and total mortality for 2-4 years.[3,12]

For the prior authorization criteria for both youth and adults:

1. Exclusionary language in those with depression or suicide (Approval criteria 5) is not supported by current evidence and should not be included. In none of the FDA labels for Qsymia, semaglutide, or tirzepatide is depression or suicide listed as a side effect, adverse outcome, or contra-indication to their use. When mentioned, labeling states "Suicidal behavior and ideation have been reported in clinical trials with other weight management products. Monitor patients treated with … and discontinue … in patients who experience suicidal thoughts or behaviors."
2. Approval Criteria 6 recommending prescription limitations of 1 month should be relaxed to the usual 90 days as tolerability is easily managed through patient education by properly prescribing providers, in the same way that metformin's (also GI intolerance) or statin's (myalgias) side effects are managed.
3. For the adults, as described above, Approval Criteria 9 is not rooted in evidence. All but 1 of each of the STEP (semaglutide) and Surmount (tirzepatide) weight loss trials included in office provider-directed instructions for patients to improve their diet quality, increase activity, and attempt a small daily calorie restriction. In the one trial for each drug that included a more structured lifestyle modification program of the type that Medicaid approves (e.g., the Diabetes Prevention Program), weight loss from both semaglutide[6] and tirzepatide[7] alone was two-fold or greater compared to intensive lifestyle behavior alone, with a non-clinically meaningful added benefit of less than 2% total weight loss (on total weight losses of 15% to 20% to drug alone) when drug therapy was combined with intensive lifestyle management. Even if such a program were readily available to all eligible patients (which it is not at present and would have to serve up to 40% of adult Oregonians currently living with obesity), requiring a Medicaid approved lifestyle modification program for use of these drugs will greatly increase the cost to Medicaid without corresponding benefit.
4. For Renewal Criteria 2, "stopping" rules of at least 5% or more per FDA recommendations only applied to earlier weight loss drugs, like Qsymia. Such specific guidelines are not applied to the GLP-1 drugs and are counter to prescribing practices for other chronic diseases. Several clinical scenarios could arise in which weight stability is equally important. These include patients that have lost substantial weight already from lifestyle programs or

after metabolic-bariatric surgery and are in the process of regaining weight. In these patients, identifying and gauging treatment response compared to a lifetime maximum weight (not baseline weight) is important. In another scenario, patients in the process of expressing unwanted weight gain of 5-10 lbs per year can gain improved appetite control and further weight gain prevention with accompanying health benefits. Other patients may lose weight initially but then experience progression of their underlying disease, showing subsequent return towards their highest weight. Like patients with type 2 diabetes who start off with metformin and then show return of A1c back to baseline, it is best to continue the initial therapy and then add another weight loss medication to augment therapy so as to re-establish a lower weight. In treating patients with the disease of obesity is best to leave obesity treatment efficacy up to the provider with recommendation to consider stopping but not require a formal “stopping” rule such as this.

Your work is very important. Removal of the antiquated and prejudiced exclusionary clause that prevents access for Oregon Medicaid patients to these important medications is a vital first step. Then, approval and coverage of medical therapy for the disease of obesity will ultimately reduce morbidity, mortality, and health care costs of covered Oregonians, many of whom are the most vulnerable and severely affected with obesity and its complications.

Thank you for your consideration.

Sincerely,

Jonathan Q Purnell, MD

References:

1. Rubino F, Puhl RM, Cummings DE, et al. Joint international consensus statement for ending stigma of obesity. Nat Med 2020;26:485-97.
2. Hampl SE, Hassink SG, Skinner AC, et al. Clinical Practice Guideline for the Evaluation and Treatment of Children and Adolescents With Obesity. Pediatrics 2023;151.
3. Lincoff AM, Brown-Frandsen K, Colhoun HM, et al. Semaglutide and Cardiovascular Outcomes in Obesity without Diabetes. N Engl J Med 2023;389:2221-32.
4. Davies M, Faerch L, Jeppesen OK, et al. Semaglutide 2.4 mg once a week in adults with overweight or obesity, and type 2 diabetes (STEP 2): a randomised, double-blind, double-dummy, placebo-controlled, phase 3 trial. Lancet 2021;397:971-84.
5. Wilding JPH, Batterham RL, Calanna S, et al. Once-Weekly Semaglutide in Adults with Overweight or Obesity. N Engl J Med 2021;384:989-1002.
6. Wadden TA, Bailey TS, Billings LK, et al. Effect of Subcutaneous Semaglutide vs Placebo as an Adjunct to Intensive Behavioral Therapy on Body Weight in Adults With Overweight or Obesity: The STEP 3 Randomized Clinical Trial. JAMA 2021;325:1403-13.
7. Aronne LJ, Sattar N, Horn DB, et al. Continued Treatment With Tirzepatide for Maintenance of Weight Reduction in Adults With Obesity: The SURMOUNT-4 Randomized Clinical Trial. JAMA 2024;331:38-48.

8. Perreault L, Davies M, Frias JP, et al. Changes in Glucose Metabolism and Glycemic Status With Once-Weekly Subcutaneous Semaglutide 2.4 mg Among Participants With Prediabetes in the STEP Program. Diabetes Care 2022;45:2396-405.
9. Borlaug BA, Kitzman DW, Davies MJ, et al. Semaglutide in HFpEF across obesity class and by body weight reduction: a prespecified analysis of the STEP-HFpEF trial. Nat Med 2023;29:2358-65.
10. Kosiborod MN, Abildstrom SZ, Borlaug BA, et al. Semaglutide in Patients with Heart Failure with Preserved Ejection Fraction and Obesity. N Engl J Med 2023;389:1069-84.
11. Rubino D, Abrahamsson N, Davies M, et al. Effect of Continued Weekly Subcutaneous Semaglutide vs Placebo on Weight Loss Maintenance in Adults With Overweight or Obesity: The STEP 4 Randomized Clinical Trial. JAMA 2021;325:1414-25.
12. Garvey WT, Batterham RL, Bhatta M, et al. Two-year effects of semaglutide in adults with overweight or obesity: the STEP 5 trial. Nat Med 2022;28:2083-91.

Chronic obesity is a complex disease, and science has proven that it's more than just calories in and calories out or a lack of will power. In 2013, the American Medical Association officially declared obesity a disease, but society still treats people affected differently than other diseases.

In the 90s, I worked long hours in a physically demanding job as a nursing assistant, while also attempting to use food as medicine, to stop my progression of becoming a person affected by obesity. None of these interventions worked for me, the treatment option of monitoring my calories and out was not successful in treating the obesity.

In 2004, I weighed 320lbs, and I had internalized much of society's negative biases. I began a low-carb diet, and I lost 100 pounds. But after 9 months, I began experiencing side effects and the restrictiveness of it was wearing on me. I sought advice from my doctor, and she told me to eat a banana. So, I went home and ate a banana. I gained 5lbs overnight, and it seemed like my body was absorbing calories triple time. I gained all of my weight back and plus some.

In my 40s, I reached my highest weight ever, 410lbs. My doctor referred me to a bariatric surgeon and I had sleeve gastrectomy surgery. With hard work and surgery, I got down to 249lbs. I still struggled with keeping my weight off.

Last year, I was able to add Ozempic to my treatment plan and lost over 30 pounds. In April of 2023, I had bariatric revision surgery due to severe GERD, but my surgeon explained that this surgery was not for weight loss. I only started to reduce weight again, after restarting Ozempic.

As a Medicare and Medicaid beneficiary, I'm afraid all of my momentum to create positive health gains will cease, because my insurance company will no longer cover Ozempic

for me. I cannot afford the $1300 out-of-pocket cost per month. My overall health improved on Ozempic. My mental health improved; A1c is within normal range; I am able to delay knee replacement surgery on both knees; my high blood pressure has improved; and my sleep apnea is almost resolved. An improvement in one aspect of my health should not open up the possibility of suffering from complication of the disease of obesity, due to being denied a medication prescribe by my doctor to best treat this disease.

So why isn't chronic obesity treated the same? I believe weight bias plays a role in the decision to deny and charge more for these medications. We must treat obesity like any other chronic disease and cover all proven treatment options. The high cost for these medications needs to be reined in like we did recently for insulin pricing.

Oregon ranks 39th in the states impacted by obesity. This makes the need for expanded access to care even more urgent. Oregon has a history of paving firsts in this nation, please let expanding anti-obesity medication coverage for all to be another. Thank you.

June 12, 2023

Setmelanotide (IMCIVREE) NEW THERAPEUTIC CLASSIFICATION

I would like to inform you that Setmelanotide injection has been reclassified in the AHFS Drug Information database managed by the American Society of Hospital Pharmacists (ASHP) from an "anti-obesity" agent to a new sub class within the "Hormone and Synthetic Substitute" category. AHFS Drug Information is the most comprehensive evidence-based source of drug information. It is the only original federal compendium whose authority for establishing accepted medical uses includes the broadest scope of drugs and indications under Medicaid, Medicare Part D, and more. In addition, it is the only drug information resource with content developed by a professional editorial and analytical staff of pharmacists for a not-for-profit scientific organization[1].

Setmelanotide's new classification is as follows:

68.00 Hormones and Synthetic Substitutes
68.48 Melanocortin Receptor Agonists
Setmelanotide

First Databank (FDB) and Wolters Kluwer Medispan Price Rx, the two main pharmaceutical pricing compendia in the United States, both license the clinical therapeutic classification from AHFS. We therefore expect that FDB and Medispan will be updating their classification of setmlanotide (IMCIVREE) shortly.

The new classification of setmelanotide (IMCIVREE) is in line with the recent reclassification from the United States Pharmacopeia Drug Classification system from "General Obesity" category to a "Genetic, Protein or Enzyme Disorder" treatment, as well as with its approved FDA indication and mechanism of action included in the USPI.

Setmelanotide (IMCIVREE) is a melanocortin 4 (MC4) receptor agonist that is an 8 amino acid cyclic peptide analog of endogenous melanocortin peptide α-MSH (alpha-melanocyte stimulating hormone). Setmelanotide may re-establish impaired MC4 receptor pathway activity arising due to genetic deficits upstream of the MC4 receptor. MC4 receptors in the brain are involved in the regulation of hunger, satiety, and energy expenditure. The approved indications of obesity due to POMC, PCSK1, or LEPR deficiency, or BBS, are associated with insufficient activation of the MC4 receptor, and result in hyperphagia, or severe pathologic hunger. Hyperphagia may lead to downstream consequences including change in eating habits, work/school performance, impact on families, and early onset severe weight gain.

Setmelanotide (IMCIVREE) does not work on pathways such as dopaminergic or opiate pathways to suppress appetite. IMCIVREE acts as a hormone replacement in the MC4 pathway to re-establish the signal of satiety for indicated patient populations that have MC4 receptor pathway impairment leading to pathologic insatiable hyperphagia (see ISI below for full indication). It is not indicated for obesity associated with other genetic syndromes and general (polygenic) obesity as stated in our US Prescribing Information.

[1] ASHP https://www.ashp.org/products-and-services/ahfs-di

FULL PRESCRIBING INFORMATION

Indication

IMCIVREE is indicated for chronic weight management in adult and pediatric patients 6 years of age and older with monogenic or syndromic obesity due to:

- Pro-opiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency as determined by an FDA-approved test demonstrating variants in *POMC*, *PCSK1*, or *LEPR* genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance (VUS)
- Bardet-Biedl syndrome (BBS)

Limitations of Use

IMCIVREE is not indicated for the treatment of patients with the following conditions as IMCIVREE would not be expected to be effective:

- Obesity due to suspected POMC, PCSK1, or LEPR deficiency with *POMC*, *PCSK1*, or *LEPR* variants classified as benign or likely benign
- Other types of obesity not related to POMC, PCSK1, or LEPR deficiency, or BBS, including obesity associated with other genetic syndromes and general (polygenic) obesity

WARNINGS AND PRECAUTIONS

Disturbance in Sexual Arousal: Spontaneous penile erections in males and sexual adverse reactions in females have occurred. Inform patients that these events may occur and instruct patients who have an erection lasting longer than 4 hours to seek emergency medical attention.

Depression and Suicidal Ideation: Depression and suicidal ideation have occurred. Monitor patients for new onset or worsening depression or suicidal thoughts or behaviors. Consider discontinuing IMCIVREE if patients experience suicidal thoughts or behaviors, or clinically significant or persistent depression symptoms occur.

Skin Pigmentation and Darkening of Pre-existing Nevi: Generalized increased skin pigmentation and darkening of pre-existing nevi have occurred. Perform a full body skin examination prior to initiation and periodically during treatment to monitor pre-existing and new pigmentary lesions.

Risk of Serious Adverse Reactions Due to Benzyl Alcohol Preservative in Neonates and Low Birth Weight Infants: IMCIVREE is not approved for use in neonates or infants. Serious and fatal

adverse reactions including “gasping syndrome” can occur in neonates and low birth weight infants treated with benzyl alcohol-preserved drugs.

ADVERSE REACTIONS

- Most common adverse reactions (incidence ≥20%) included skin hyperpigmentation, injection site reactions, nausea, headache, diarrhea, abdominal pain, vomiting, depression, and spontaneous penile erection

USE IN SPECIFIC POPULATIONS

Treatment with IMCIVREE is not recommended when breastfeeding. Discontinue IMCIVREE when pregnancy is recognized unless the benefits of therapy outweigh the potential risks to the fetus.

To report SUSPECTED ADVERSE REACTIONS, contact Rhythm Pharmaceuticals at 833-789-6337 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see the full Prescribing Information for additional Important Safety Information.