Clinical Policy: Obesity Treatment Agents

Reference Number: PHW.PDL.750
Effective Date: 01/09/2023
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Revision Log

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of PA Health & Wellness® that Obesity Treatment Agents is **medically necessary** when the following criteria are met:

I. Requirements for Prior Authorization of Obesity Treatment Agents

A. Prescriptions That Require Prior Authorization

All prescriptions for Obesity Treatment Agents must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Obesity Treatment Agent, the determination of whether the requested prescription is medically necessary will take into account whether the member:

1. For a request for Evekeo (amphetamine) for any indication other than the treatment of obesity, see PHW.PDL.007 Stimulants and Related Agents; **OR**

2. For beneficiaries 18 years of age and older, **one** of the following:

   a. Has a body mass index (BMI) greater than or equal to 30 kg/m^2

   b. **Both** of the following:

      i. **One** of the following:

         a) Has a BMI greater than or equal to 27 kg/m^2 and less than 30 kg/m^2
         b) Has been determined by the prescriber to be a candidate for treatment based on degree of adiposity, waist circumference, history of bariatric surgery, BMI exceptions for the member's ethnicity, etc.

      ii. Has at least **one** weight-related comorbidity as determined by the prescriber, such as dyslipidemia, hypertension, type 2 diabetes, prediabetes, obstructive sleep apnea, metabolic syndrome, etc.;

   AND

3. For beneficiaries less than 18 years of age, has a BMI in the 95th percentile or greater standardized for age and sex based on current Centers for Disease Control and Prevention (CDC) charts; **AND**

4. Has been counseled about lifestyle changes and behavioral modification (e.g., healthy diet and increased physical activity); **AND**

5. Is age- and weight-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND

6. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND

7. Does not have a contraindication to the prescribed medication; AND

8. For Evekeo (amphetamine), **all** of the following:

    a. Was assessed for potential risk of misuse, abuse, or addiction based on family and social history obtained by the prescribing provider,

    b. Has documentation that the member has been educated on the potential adverse effects of stimulants, including the risk for misuse, abuse, and addiction,

    c. For a member with a history of comorbid substance dependency, abuse, or diversion, has results of a recent urine drug screen testing for licit and illicit drugs with the potential for abuse (including specific testing for oxycodone, fentanyl, and tramadol) that is consistent with prescribed controlled substances,

    d. **Both** of the following:

        i. Has a history of trial and failure of or a contraindication or an intolerance to all other Obesity Treatment Agents (preferred and non-preferred)
        ii. Has documentation from the prescriber explaining the rationale for why the requested medication is needed and a plan for tapering;

    AND

9. For all other non-preferred Obesity Treatment Agents, has history of therapeutic failure of or a contraindication or an intolerance to the preferred Obesity Treatment Agents approved or medically accepted for the member's diagnosis or indication;

See the Preferred Drug List (PDL) for the list of preferred Obesity Treatment Agents at: https://papdl.com/preferred-drug-list;

AND

10. For therapeutic duplication, **one** of the following:

    a. For a glucagon-like peptide-1 (GLP-1) receptor agonist, is being titrated to or tapered from a dipeptidyl peptidase-4 (DPP-4) inhibitor or another GLP-1 receptor agonist,
    b. For a stimulant agent, is being titrated to or tapered from another stimulant agent,
    c. Has a medical reason for concomitant use of the requested medications that is supported by peer-reviewed medical literature or national treatment guidelines;

    AND

11. If a prescription for an Obesity Treatment Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in PA.CP.PMN.59 Quantity Limit Override.

    NOTE: If the member does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the member, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR OBESITY TREATMENT AGENTS: The determination of medical necessity of a request for renewal of a prior authorization for an Obesity Treatment Agent that was previously approved will take into account whether the member:

1. For beneficiaries 18 years of age and older, **one** of the following:

    a. Is continuing with dose titration,
    b. Experienced a percent reduction of baseline body weight that is consistent with the recommended cutoff in FDA-approved package labeling, peer-reviewed medical literature, or consensus treatment guidelines after 3 months of therapy with the maximum recommended/tolerated dose,
    c. Continues to experience clinical benefit from the Obesity Treatment Agent based on the prescriber's assessment;

    AND

2. For beneficiaries less than 18 years of age, one of the following:

    a. Is continuing with dose titration,
    b. Experienced a percent reduction of baseline BMI or BMI z-score that is consistent with the recommended cutoff in FDA-approved package labeling, peer-reviewed medical literature, or consensus treatment guidelines after 3 months of therapy with the maximum recommended/tolerated dose,
    c. Continues to experience clinical benefit from the Obesity Treatment Agent based

on the prescriber's assessment;

AND

3. Has been counseled about lifestyle changes and behavioral modification (e.g., healthy diet and increased physical activity); **AND**

4. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND

5. Does not have a contraindication to the prescribed medication; AND

6. For Evekeo (amphetamine), **both** of the following:

   a. For a member with a history of comorbid substance dependency, abuse, or diversion, has results of a recent urine drug screen testing for licit and illicit drugs with the potential for abuse (including specific testing for oxycodone, fentanyl, and tramadol) that is consistent with prescribed controlled substances
   b. Has documentation from the prescriber explaining the rationale for why the requested medication continues to be needed and plan for tapering;

   AND

7. For all other non-preferred Obesity Treatment Agents, has history of therapeutic failure of or a contraindication or an intolerance to the preferred Obesity Treatment Agents approved or medically accepted for the member's diagnosis or indication;

   See the Preferred Drug List (PDL) for the list of preferred Obesity Treatment Agents at: https://papdl.com/preferred-drug-list;

   AND

8. For therapeutic duplication, **one** of the following:

   a. For a GLP-1 receptor agonist, is being titrated to or tapered from a DPP-4 inhibitor or another GLP-1 receptor agonist,
   b. For a stimulant agent, is being titrated to or tapered from another stimulant agent,
   c. Has a medical reason for concomitant use of the requested medications that is supported by peer-reviewed medical literature or national treatment guidelines;

   AND

9. If a prescription for an Obesity Treatment Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in PA.CP.PMN.59 Quantity Limit Override.

NOTE: If the member does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the member, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Obesity Treatment Agents. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the member

D. Approval Duration:

Requests for prior authorization of Obesity Treatment Agents will be approved as follows:

1. For Evekeo (amphetamine), all requests will be approved for up to 3 months.
2. For a GLP-1 receptor agonist (e.g., Saxenda or Wegovy), all requests will be approved for up to 6 months.
3. For all other Obesity Treatment Agents:
   a. Initial requests for prior authorization will be approved for up to 4 months.
   b. Renewals of requests for prior authorization will be approved for up to 6 months.

E. References

1. Adipex-P Package Insert. Parsippany, NJ: Teva Pharmaceuticals; September 2020.
2. Apovian CM, Aronne LJ, Bessesen DH, McDonnell ME, Murad MH, Pagotto U, Ryan DH, Still CD; Endocrine Society. Pharmacological management of obesity: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2015 Feb;100(2):342-62. doi: 10.1210/jc.2014-3415. Epub 2015 Jan 15. Erratum in: J Clin Endocrinol Metab. 2015 May;100(5):2135-6. PMID: 25590212.
3. Atlas SJ, Kim K, Beinfeld M, Lancaster V, Nhan E, Lien PW, Shah K, Touchette DR, Moradi A, Rind DM, Pearson SD, Beaudoin, F. Medications for Obesity Management: Effectiveness and Value; Draft Evidence Report. Institute for Clinical and Economic Review, July 13, 2022. https://icer.org/assessment/obesity-management-2022/.
4. Benzphetamine Package Insert. Newtown, PA:KVK-Tech, INC.; June 2022.
5. Bray GA. Why do we need drugs to treat the patient with obesity? Obesity (Silver Spring). 2013 May;21(5):893-9. doi: 10.1002/oby.20394. PMID: 23520198.
6. Cole TJ, Bellizzi MC, Flegal KM, Dietz WH. Establishing a standard definition for child overweight and obesity worldwide: international survey. BMJ. 2000 May 6;320(7244):1240-3. doi: 10.1136/bmj.320.7244.1240. PMID: 10797032; PMCID: PMC27365.
7. Diethylpropion Package Insert. Newtown, PA: KVK-Tech, INC.; December 2018.

8. Diethylpropion Extended Release Package Insert. Philadelphia, PA: Lannett Company, Inc; December 2019.
9. Garvey WT, Mechanick JI, Brett EM, et al. American Association of Clinical Endocrinologists and American College of Endocrinology comprehensive clinical practice guidelines for medical care of patients with obesity. Endocr Pract 2016;22 Suppl 3:1-203.
10. 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(2): e2022060640
11. Khera R, Murad MH, Chandar AK, et al. Association of Pharmacological Treatments for Obesity With Weight Loss and Adverse Events: A Systematic Review and Meta-analysis. JAMA. 2016;315(22):2424–2434. doi:10.1001/jama.2016.7602
12. Perreault L. Obesity in adults: Drug therapy. Pi-Sunyer FX, Swenson S eds. Waltham MA: UpToDate Inc. Updated August 08, 2023. Accessed August 21, 2023.
13. Phendimetrazine Package Insert. Newtown, PA: KVK-Tech, INC.; December 2019.
14. Phendimetrazine Extended-Release Package Insert. Langhorne, PA: Virtus Pharmaceuticals, LLC; October 2022.
15. Phentermine Package Insert. Newtown, PA: KVK-Tech INC.; December 2018.
16. Ryan DH, Kahan S. Guideline recommendations for obesity management. Med Clin N Am 2018;102:49-63.
17. Saxenda Package Insert. Plainsboro, NJ: Novo Nordisk Inc.; April 2023.
18. Skelton JA. Prevention and management of childhood obesity in the primary care setting. Lorin MI, Motil KJ, Heyman MB, Hoppin AG eds. Waltham MA: UpToDate Inc. Updated July 14, 2023. Accessed August 21, 2023.
19. Shi Q, Wang Y, Hao Q, et al. Pharmacotherapy for adults with overweight and obesity: a systematic review and network meta-analysis of randomised controlled trials. Lancet 2021;399:259-69.
20. Son JW, Kim S. Comprehensive Review of Current and Upcoming Anti-Obesity Drugs. Diabetes Metab J. 2020;44(6):802-818. doi:10.4093/dmj.2020.0258
21. Styne DM, Arslanian SA, Connor EL, Farooqi IS, Murad MH, Silverstein JH, Yanovski JA. Pediatric Obesity-Assessment, Treatment, and Prevention: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2017 Mar 1;102(3):709-757. doi: 10.1210/jc.2016-2573. PMID: 28359099; PMCID: PMC6283429.
22. Tak YJ, Lee SY. Anti-Obesity Drugs: Long-Term Efficacy and Safety: An Updated Review. World J Mens Health. 2021 Apr;39(2):208-221. https://doi.org/10.5534/wjmh.200010
23. Velazquez A, Apovian CM. Updates on obesity pharmacotherapy. Ann N Y Acad Sci. 2018 Jan;1411(1):106-119. doi: 10.1111/nyas.13542. PMID: 29377198.
24. Wegovy Package Insert. Plainsboro NJ: Novo Nordisk Inc.; July 2023.
25. Wharton, S, Lau DCW, Vallis M, et al. Obesity in adults: a clinical practice guideline. CMAJ 2020;192:e875-91.
26. Williams, D.M., Nawaz, A. & Evans, M. Drug Therapy in Obesity: A Review of Current and Emerging Treatments. Diabetes Ther 11, 1199–1216 (2020). https://doi.org/10.1007/s13300-020-00816-y
27. Xenical Package Insert. Montgomery, AL: H2-Pharma, LLC; November 2022.

Reviews, Revisions, and Approvals	Date
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