Medical Policy

Off-Label Use of FDA-Approved Drugs and Biologicals	
MEDICAL POLICY NUMBER	Med_Clin_Ops_077
ORIGINAL EFFECTIVE DATE	July 19, 2021
CURRENT VERSION EFFECTIVE DATE	January 1, 2024
APPLICABLE PRODUCT AND MARKET	*Individual Family Plan:* All Plans *Small Group*: All Plans *Medicare Advantage:* All Plans

Brand New Day/Central Health Medicare Plan develops policies and makes coverage determinations using credible scientific evidence including but not limited to MCG™ Health Guidelines, the ASAM Criteria™, and other third party sources, such as peer-reviewed medical literature generally recognized by the relevant medical community, physician specialty society recommendations, and expert opinion as relevant to supplement those sources. Brand New Day/Central Health Medicare Plan Medical Policies, MCG™ Guidelines, and the ASAM Criteria™ are not intended to be used without the independent clinical judgment of a qualified health care provider considering the individual circumstances of each member's case. The treating health care providers are solely responsible for diagnosis, treatment, and medical advice. Members may contact Brand New Day/Central Health Medicare Plan Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Brand New Day/Central Health Medicare Plan Medical Policy may contact the Health Plan. Brand New Day/Central Health Medicare Plan policies and practices are compliant with federal and state requirements, including mental health parity laws.

If there is a difference between this policy and the member specific plan document, the member benefit plan document will govern. For Medicare Advantage members, Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), govern. Refer to the CMS website at http://www.cms.gov for additional information.

Brand New Day/Central Health Medicare Plan medical policies address technology assessment of new and emerging treatments, devices, drugs, etc. They are developed to assist in administering plan benefits and do not constitute an offer of coverage nor medical advice. Brand New Day/Central Health Medicare Plan medical policies contain only a partial, general description of plan or program benefits and do not constitute a contract. Brand New Day/Central Health Medicare Plan does not provide health care services and, therefore, cannot guarantee any results or outcomes. Treating providers are solely responsible for medical advice and treatment of members. Our medical policies are updated based on changes in the evidence and healthcare coding and therefore are subject to change without notice. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). MCG™ and Care Guidelines® are trademarks of MCG Health, LLC (MCG).

PURPOSE

To promote consistency between reviewers in clinical coverage decision-making by providing the criteria that generally determine the medical necessity of Off-Label indications for FDA-Approved Drugs and Biologicals.

Note: This medical policy applies to drugs/biologics for which no specific policy or Plan guideline exists

POLICY/CRITERIA

Prior Authorization and Medical Review is required.

The requested drug/biologic may be determined medically necessary for the requested off-label indication when **ALL** of the criteria are met:

1. The requested drug/biologic is approved by the U.S. Food and Drug Administration; **AND**

Off-Label Indications

2. The requested drug/biologic has not been excluded from coverage due to lack of efficacy, clinical benefit, or administrative program (e.g., exclusion at launch, plan document); **AND**
3. The patient has not failed a previous trial of the requested drug/biologic; **AND**
4. The requested drug/biologic is not part of an eligible clinical trial; **AND**
5. The patient has a documented history of failure, contraindication, or intolerance to standard, conventional therapies to treat or manage the disease or condition, where available; **AND**
6. The requested indication is clinically supported as a use by at least one of the following:
    a. Drug Compendia:
        i. American Hospital Formulary Service Drug Information (AHFS-DI): Therapeutic Uses
        ii. Clinical Pharmacology: Quality of Evidence High or Moderate and Strength of Recommendation Strong
        iii. NCCN Drugs and Biologics Compendium: Categories of Consensus I and IIa
        iv. Micromedex DrugDex: Class I, Class IIa, or Class IIb.
        v. Lexi-Drugs: Evidence Level A
    b. Two (2) articles from major peer reviewed medical journals* that present data supporting the proposed off-label use as safe and effective unless there is validated and uncontested contradictory evidence presented in a major peer-reviewed medical journal. For consideration of off-label usage, copies of relevant full-text articles from the peer-reviewed literature must be submitted.**

    **Acceptable peer reviewed medical journals include, but are not limited to, Journal of American Medical Association, New England Journal of Medicine, and Lancet. Evidence limited to case studies or case series is not sufficient to meet the standard of this criterion. **Studies submitted for review must come from different centers and be published in national or international peer-reviewed journals (with editorial committees comprised of physicians).*

LIMITATIONS/EXCLUSIONS

1. If the requested use is identified as **not indicated** by CMS (in the case of Medicare members) or the FDA, or if a use is specifically identified as not indicated in at least one of the two (2) major compendia, or it is determined (based on peer-reviewed literature) that the drug/biologic is not safe and effective, then the off-label usage is not supported and therefore not covered.
2. Patient's previously receiving the requested drug as part of a manufacturing copay or coupon program will not be covered as continuation of care if the prior authorization criteria contained in this policy are not met.

Note: Services related to noncovered services are not covered (e.g., administration services).

DEFINITIONS

FDA-approved indication: An indication depicted on the drug/biologic's official label with

prescribing instructions, which includes, but is not necessarily limited to, dosage, route of administration, duration and frequency of administration and population to whom the drug would be administered.

Off-label (also referred to as unlabeled or non-FDA-approved) usage: Drug/biologic usage for an indication that is not listed on the official label; further defined as administration of the drug/biologic in a way that deviates significantly from the prescribing information on the official label for a particular indication. This includes, but is not necessarily limited to, dosage, route of administration, duration and frequency of administration and population to whom the drug would be administered.

Medically accepted indication:

- Usage consistent with FDA-approved indication (labeled indication)
- Articles or Local Coverage Determinations (LCDs) or National Coverage Determinations (NCDs) published by National Government Services
- Usage supported by ≥1 citations in at least 1 of the following drug compendia:
  - American Hospital Formulary Service Drug Information (AHFS-DI): Therapeutic Uses
  - Clinical Pharmacology: Quality of Evidence High or Moderate and Strength of Recommendation Strong
  - NCCN Drugs and Biologics Compendium: Categories of Consensus I and IIa
  - Micromedex DrugDex: Class I, Class IIa, or Class IIb.
  - Lexi-Drugs: Evidence Level A

EVIDENCE BASED REFERENCES

1. AHFS Drug information [website]. Available at: http://www.ahfsdruginformation.com/levels-of-evidence-rating-system/. Accessed June, 2021.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; insert current year of copyright. URL: http://www.clinicalpharmacology.com. Accessed June, 2021.
3. IBM Micromedex® DRUGDEX® (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. Available at: http://www.micromedexsolutions.com/. Accessed June, 2021.
4. 42 CFR § 414.930. Available at: www.CMS.gov. Accessed June, 2021.
5. U.S. Food and Drug Administration Regulatory Information [website]. "Off-Label" and Investigational Use of Marketed Drugs, Biologics, and Medical Devices - Information Sheet. http://www.fda.gov/RegulatoryInformation/Guidances/ucm126486.htm. Accessed June, 2021.

POLICY HISTORY

Original Effective Date	July 19, 2021
Revised Date	November 1 2021 January 1, 2024 - Updated to Brand New Day/Central Health Medicare Plan (no policy revisions made)
Approval Body	Pharmacy and Therapeutics Committee