Pharmacy Medical Necessity Guidelines: Anti-emetic Medications

Effective: February 9, 2021

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM

These pharmacy medical necessity guidelines apply to the following:

Commercial Products

☐ Tufts Health Plan Commercial products – large group plans
☐ Tufts Health Plan Commercial products – small group and individual plans
☐ Tufts Health Freedom Plan products – large group plans
☐ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☐ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:
RXUM: 617.673.0988

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Cesamet (nabilone) is indicated for the treatment of the nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional antiemetic treatments. This restriction is required because a substantial proportion of any group of patients treated with Cesamet (nabilone) can be expected to experience disturbing psychotomimetic reactions not observed with other antiemetic agents.

Syndros (dronabinol oral solution) is a cannabinoid indicated in adults for the treatment of anorexia associated with weight loss in patients with AIDS and nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional antiemetic therapies. Dronabinol is available as capsules and oral solution. Dronabinol capsules are the preferred formulation for Tufts Health Together.

Diclegis (doxylamine/pyridoxine) and Bonjesta (doxylamine/pyridoxine ER) are indicated for the treatment of nausea and vomiting of pregnancy in women who do not respond to conservative management.

Sancuso (granisetron) is a serotonin-3 (5-HT3) receptor antagonist indicated for the prevention of nausea and vomiting in patients receiving moderately and/or highly emetogenic chemotherapy for up to five consecutive days.

Syndros (dronabinol oral solution) is indicated for the treatment of anorexia associated with weight loss in patients with AIDS as well as nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional antiemetic treatments.

COVERAGE GUIDELINES

The plan may authorize coverage of a non-preferred anti-emetic medication for Members when **all** the following criteria are met:

Doxylamine/pyridoxine (Diclegis)

1. The Member is diagnosed with nausea and vomiting associated with pregnancy

AND

2. The Member tried and failed concurrent therapy with over-the counter doxylamine and pyridoxine, or the provider indicates clinical inappropriateness of treatment with the concurrent use of over-the-counter doxylamine and pyridoxine

Doxylamine/pyridoxine ER (Bonjesta)

1. The Member is diagnosed with nausea and vomiting associated with pregnancy

AND

2. The Member tried and failed concurrent therapy with over-the counter doxylamine and pyridoxine, or the provider indicates clinical inappropriateness of treatment with the concurrent use of over-the counter doxylamine and pyridoxine

AND

3. The Member has had an inadequate response to Diclegis (doxylamine/pyridoxine)

Dronabinol oral solution (Syndros)

1. The Member has one of the following diagnoses:
    a. Anorexia associated with weight loss in patients with AIDS
    b. Nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional antiemetic treatments

AND

2. Provider indicates a clinical rationale why the Member is unable to administer generic dronabinol oral capsules (e.g., swallowing difficulties)

Granisetron transdermal (Sancuso)

1. The Member is receiving emetogenic chemotherapy for a duration of at least 5 consecutive days

Nabilone (Cesamet)

1. The Member has tried and failed therapy with at least two first line antiemetic agents (e.g., ondansetron, aprepitant, dexamethasone).

LIMITATIONS

1. Sancuso (granisetron) is limited to one transdermal patch per 7 days, not to exceed 4 patches per 28 days.
2. Approval duration of Diclegis (doxylamine/pyridoxine) and Bonjesta (doxylamine/pyridoxine) is nine months.

CODES

None

REFERENCES

1. Arsenault MY, Lane CA, et al. The management of nausea and vomiting of pregnancy. *Journal of Obstetrics and Gynaecology Canada*. 2002;24(10):817-23. Available at: sogc.org/guidelines/the-management-of-nausea-vomiting-of-pregnancy/. Accessed 2016 June 22.
2. Bonjesta (doxyamine/pyridoxine ER) [prescribing information]. Bryn Mawr, PA: Duchesnay USA, Inc; June 2018.
3. Cesamet (nabilone) [prescribing information]. Bridgewater, NJ: Bausch Health US, LLC; March 2020.
4. Diclegis (doxylamine/pyridoxine) [package insert]. Bryn Mawr, PA: Duchesnay USA; June 2018.
5. Koren G, Clark S, Hankins GDV, et al. Effectiveness of delayed-release doxylamine and pyridoxine for nausea and vomiting of pregnancy: a randomized placebo controlled trial. *Am J Obstet Gynecol*. 2010;203(6):571.e1-7.
6. Sancuso (granisetron) [prescribing information]. Bedminster, NJ: Kywona Kirin, Inc; April 2020.
7. Syndros (dronabinol) [prescribing information]. Chandler, AZ: Insys Therapeutics, Inc; September 2018.
8.

APPROVAL HISTORY

July 8, 2014: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. July 14, 2015: Non-covered medications and QL criteria removed; incorporated criteria for Cesamet and Diclegis.
2. January 1, 2016: Administrative change to rebranded template.
3. July 12, 2016: No changes.
4. May 9, 2017: Administrative update, Adding Tufts Health RITogether to the template.
5. July 11, 2017: Clarified the quantity limit for Sancuso (granisetron transdermal). Effective 1/1/18, specified that two first line agents need to be trialed for approval of Cesamet.
6. September 12, 2017: Added criteria for Syndros (dronabinol oral solution).
7. April 10, 2018: Added criteria for Bonjesta (doxylamine/pyridoxine ER) to the MNG.
8. March 12, 2019: Administrative changes made to template.
9. August 11, 2020: No changes.
10. February 9, 2021: No changes.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.

Provider Services