

Doxylamine succinate and pyridoxine delayed release tablets
Effective 12/01/2019

Plan	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit		
Specialty Limitations	N/A		
Contact Information	Medical and Specialty Medications		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
Exceptions	Non-Specialty Medications		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029

Overview

Doxylamine with pyridoxine delayed-release tablets (10mg/10mg or Bonjesta 20mg/20mg) are indicated for the treatment of nausea and vomiting of pregnancy in women who do not respond to conservative management.

Coverage Guidelines

Authorization may be granted for members new to the plan who are currently receiving treatment with doxylamine with pyridoxine delayed release tablets (10mg/10mg) or Bonjesta excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization may be granted if the member meets all following criteria and documentation has been submitted:

1. The member has a diagnosis of nausea and vomiting associated with an active pregnancy
2. The member has had an inadequate response to combination therapy with pyridoxine and doxylamine taken concurrently.

OR

3. The provider submits clinical rationale why treatment with the concurrent use of pyridoxine and doxylamine is not appropriate.

Limitations

1. Initial approvals will be for a duration of 4 months.
2. Reauthorizations may be granted for up to an additional 6 months.
3. The following quantity limits apply:

Doxylamine with pyridoxine 10mg/10mg	#120 tablets per 30 days
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References

1. Bonjesta (doxylamine and pyridoxine) [prescribing information]. Bryn Mawr, PA: Duchesnay USA; November 2017Mulpleta (lusutrombopag) [prescribing information]. Florham Park, NJ: Shionogi Inc; July 2018.
2. Doxylamine/pyridoxine [prescribing information]. Actavis Laboratories; January 2019
3. Koren G, Hankins GD, Clark S, et al. Effectiveness of doxylamine-pyridoxine for morning sickness. Am J Obstet Gynecol 2016; 214:664.
4. Fiaschi L, Nelson-Piercy C, Deb S, et al. Clinical management of nausea and vomiting in pregnancy and hyperemesis gravidarum across primary and secondary care: a population-based study. BJOG 2019; 126:1201

Review History

2014 – Implementation

02/20/19 – Reviewed

04/27/15 – Reviewed

02/22/16 – Reviewed

02/27/17 – Reviewed

03/22/18 – Added Bonjesta

09/24/18 – Updated references

09/18/19 – Generic Diclegis

09/16/20 – Reviewed at P&T

11/16/2022 – Reviewed for Nov P&T. Separated out MH vs Comm/Exch. No clinical changes.

