

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

<b>Plan</b>	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	<b>Program Type</b>	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
<b>Benefit</b>	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit (NLX)		
<b>Specialty Limitations</b>	N/A		
<b>Contact Information</b>	<b>Specialty Medications</b>		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	<b>Non-Specialty Medications</b>		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	<b>Medical Specialty Medications (NLX)</b>		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
<b>Exceptions</b>	N/A		

### 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.

