

Doxylamine succinate and pyridoxine delayed release tablets
Effective 12/1/2019

Plan	<input checked="" type="checkbox"/> MassHealth <input checked="" type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit (NLX)		<input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Specialty Limitations	N/A		
Contact Information	Specialty Medications		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	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
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	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 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 2017
2. Diclegis (doxylamine/pyridoxine) [prescribing information]. Bryn Mawr, PA: Duchesnay USA; April 2013
3. Koren G, Clark S, Hankins GD, et al. Maternal safety of the delayed-release doxylamine and pyridoxine combination for nausea and vomiting of pregnancy; a randomized placebo controlled trial. *BMC Pregnancy Childbirth* 2015; 15:59.
4. American College of Obstetricians and Gynecologists (ACOG). Practice Bulletin No. 153: Nausea and Vomiting of Pregnancy. *Obstet Gynecol.* 2015;126(3):e12-e24.[PubMed 26287788]10.1097/AOG.0000000000001048

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

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