Bonjesta, Diclegis
Prior Authorization with Quantity Limit Criteria

This program applies to FlexRx Open, FlexRx Closed, GenRx Open, GenRx Closed, Health Insurance Marketplace and KeyRx formularies.

This is a FlexRx Standard and GenRx Standard program.

FDA APPROVED INDICATIONS AND DOSAGE[1,2]

Agent	Indication	Dosage & Administration	
Bonjesta (doxylamine/pyridoxine ER) tablets	Treatment of nausea and vomiting of pregnancy in women who do not respond to conservative management. Limitation of use: Bonjesta has not been studied in women with hyperemesis gravidarum	On Day 1, take one tablet at bedtime. On Day 2, if symptoms are not adequately controlled, the dose can be increased to one tablet in the morning and one tablet at bedtime. The maximum recommended dose is two tablets daily, one in the morning and one at bedtime.	
Diclegis® (doxylamine/pyridoxyine delayed release) tablet	Treatment of nausea and vomiting of pregnancy in women who do not respond to conservative management. Limitation of use: Diclegis has not been studied in women with hyperemesis gravidarum	Take two tablets daily at bedtime. If symptoms are not adequately controlled, the dose can be increased to a maximum recommended dose of four tablets daily (one in the morning, one mid-afternoon and two at bedtime).	

CLINICAL RATIONALE

Guidelines

Pyridoxine is recommended as a first line treatment for pregnant women who have mild nausea and infrequent vomitting.[3,4] As a single agent, pyridoxine for pregnancy related nausea and vomiting is usually dosed as 10-25 mg orally every 6-8 hours.[3]

For individuals who have nausea with frequent vomiting or for those who require additional treatment on top of dietary changes, trigger avoidance, and or pyridoxine, antihistamines (doxylamine, diphenhydramine, meclizine, dimenhydrinate) are recommended as first line.[3,4]

Both pyridoxine and doxylamine are available over the counter.[3]

Safety

Bonjesta has the following contraindications:[1]

- Known hypersensitivity to doxylamine succinate, other ethanolamine derivative antihistamines, pyridoxine hydrochloride or any inactive ingredient in the formulation
- Monoamine oxidase (MAO) inhibitors

Diclegis has the following contrainidcations:[2]

- Known hypersensitivity to doxylamine succinate, other ethanolamine derivative antihistamines, pyridoxine hydrochloride or any inactive ingredient in the formulation
- Monoamine oxidase (MAO) inhibitors

REFERENCES

1. Bonjesta prescribing information. Duchesnay, Inc. November 2016.
2. Diclegis prescribing information. Duchesnay, Inc. September 2013.
3. Treatment and outcome of nausea and vomiting of pregnancy. UptoDate. Last updated 1/3/2017. Accessed 2/27/2017.
4. ACOG Guidelines at a Glance: Nausea and Vomiting of Pregnancy. Available at: http://contemporaryobgyn.modernmedicine.com/contemporary-obgyn/news/acog-guidelines-glance-nausea-and-vomiting-pregnancy. Accessed 2/27/2017.

Document History

Original Prime Standard Criteria approved by P&T UM Committee April 2017
Original Client Specific Review Prime Standard criteria, approved by BCBS M Pharmacy Clinical Team (PCT) 11/2017
Original Implementation 2/1/18
Administrative Action (addition of Bonjesta GPI information) 03/2018
Annual Review Prime Standard criteria, maintained, approved by P&T UM Committee 6/2018
Client Specific Annual Review Prime Standard criteria, maintained, approved by BCBS M PCT 06/2018

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OBJECTIVE
The intent of the program is to ensure appropriate use based on FDA labeling, guidelines, or clinical studies. The program encourages the trial of the ingredients within the target agent together as separate dosage forms. The program accommodates for when the prescriber has provided documentation that the use of the individual ingredients within the target agent together as separate dosage forms is not clinically appropriate.

TARGET AGENTS FOR PRIOR AUTHORIZATION AND QUANTITY LIMIT(S)

Brand (generic)	GPI	Multisource Code	Quantity Limit Per Day
Bonjesta (doxylamine/pyridoxine ER)			
20 mg / 20 mg	50309902100430	M, N, O, Y	2 tablets
Diclegis (doxylamine/pyridoxine delayed release)			
10 mg / 10 mg	50309902100620	M, N, O, Y	4 tablets

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL
TARGET AGENT(S) will be approved when ALL of the following are met:

1. The requested agent is being used to treat pregnancy related nausea or vomiting (not including hyperemesis gravidarum)
   AND
2. The prescriber has provided documentation that the use of the individual ingredients within the target combination agent as separate dosage forms is not clinically appropriate for the patient
   AND
3. The patient does NOT have any FDA labeled contraindication(s) to the requested agent
   AND
4. ONE of the following:
   a. The quantity requested is less than or equal to the program quantity limit
      OR
   b. The quantity (dose) requested is above the program limit, less than or equal to the maximum dose recommended in FDA approved labeling and the prescribed dose cannot be achieved using a lesser quantity of a higher strength
      OR
   c. The quantity (dose) requested is greater than the maximum dose recommended in FDA approved labeling and the prescriber has submitted documentation in support of therapy with a higher dose for the intended diagnosis which has been reviewed and approved by the Clinical Review pharmacist

Length of approval: 12 months

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ELECTRONIC EDIT
The overall process for a prior authorization will not allow the targeted drugs to adjudicate through the claims system. When a patient requests a targeted drug the system will reject the claim with the message indicating that prior authorization is necessary.

PRIOR AUTHORIZATION CRITERIA QUESTION SET
Evaluation

1. Is the requested agent being used to treat pregnancy related nausea or vomiting (not including hyperemesis gravidarum)?
   If yes, continue to 2.
   If no, deny.

2. Has the prescriber provided documentation that the use of the individual ingredients within the target combination agent as separate dosage forms is not clinically appropriate for the patient?
   If yes, pharmacist must review and may continue to 3.
   If no, deny.

3. Does the patient have any FDA labeled contraindication(s) to the requested agent (please see table)?
   If yes, deny.
   If no, continue to 4.

4. Is the quantity requested greater than the set limit?
   If yes, continue to 5.
   If no, approve for 12 months.

5. Is the quantity requested greater than the maximum dose recommended in FDA approved labeling?
   If yes, continue to 7.
   If no, continue to 6.

6. Can the prescribed dose be achieved with a lower quantity of a higher strength that does not exceed the limit?
   If yes, deny increased quantity requested and approve the PA for the set limit for 12 months.
   If no, approve quantity requested for 12 months.

7. Has the prescriber submitted documentation in support of therapy for an accepted diagnosis for exception?
   If yes, pharmacist must review and may approve quantity requested for 12 months based on review of information provided.
   If no, deny for higher quantity and approve within program quantity limit for 12 months.

FDA Labeled Contraindications

Agent	Contraindication(s)
Bonjesta (doxylamine/pyridoxine ER)	Known hypersensitivity to doxylamine succinate, other ethanolamine derivative antihistamines, pyridoxine hydrochloride or any inactive ingredient in the formulation Monoamine oxidase (MAO) inhibitors
Diclegis (doxylamine/pyridoxine ER)	Known hypersensitivity to doxylamine succinate, other ethanolamine derivative antihistamines, pyridoxine hydrochloride or any inactive ingredient in the formulation Monoamine oxidase (MAO) inhibitors