Bonjesta, Diclegis
Prior Authorization with Quantity Limit Program Summary

This prior authorization applies Commercial, NetResults F series and Health Insurance Marketplace formularies.

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

This pharmacy policy is not an authorization, certification, explanation of benefits or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All pharmacy policies are based on (i) information in FDA approved package inserts (and black box warning, alerts, or other information disseminated by the FDA as applicable); (ii) research of current medical and pharmacy literature; and/or (iii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

The purpose of Blue Cross and Blue Shield of Alabama's pharmacy policies are to provide a guide to coverage. Pharmacy policies are

not intended to dictate to physicians how to practice medicine. Physicians should exercise their medical judgment in providing the care they feel is most appropriate for their patients.

Neither this policy, nor the successful adjudication of a pharmacy claim, is guarantee of payment.

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.