Bonjesta, Diclegis Prior Authorization with Quantity Limit Program Summary

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

This is a FlexRx Standard and GenRx Standard program.

POLICY REVIEW CYCLE

Effective Date	Date of Origin
11/1/2023	2/1/2018

FDA APPROVED INDICATIONS AND DOSAGE

Agent(s)	FDA Indication(s)	Notes	Ref#
Bonjesta® (doxylamine/pyridoxine ER) Tablet	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		1
Diclegis® (doxylamine/pyridoxine 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	*generic available	2

See package insert for FDA prescribing information: https://dailymed.nlm.nih.gov/dailymed/index.cfm

CLINICAL RATIONALE

Guidelines	Pyridoxine (Vitamin B_6) is recommended as a first line pharmacologic treatment for pregnant women who have nausea and vomiting, either taken alone or with the antihistamine doxylamine. As a single agents, pyridoxine for pregnancy related nausea and vomiting is usually dosed as 10-25 mg orally 3 or 4 times a day, while doxylamine is doses as 12.5 mg also 3 or 4 times a day. An additional antihistamine (dimenhydrinate, diphenhydramine, prochlorperazine, or promethazine) may be added to the pyridoxine and doxylamine combination if symptoms are persistent. 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 contraindications:(2) • Known hypersensitivity to doxylamine succinate, other ethanolamine derivative antihistamines, pyridoxine hydrochloride or any inactive ingredient in the formulation

	• Monoamine oxidase (MAO) inhibitors

REFERENCES

Number	Reference
1	Bonjesta prescribing information. Duchesnay, Inc. June 2022.
2	Diclegis prescribing information. Duchesnay, Inc. October 2022.
3	ACOG Practice Bulletin: Nausea and Vomiting of Pregnancy. Obstetrics and Gynecology, 131:1, January 2018. https://www.ncbi.nlm.nih.gov/pubmed/29266076.

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Diclegis	doxylamine-pyridoxine tab delayed release	10-10 MG	M ; N ; O ; Y	O ; Y		
Bonjesta	doxylamine-pyridoxine tab er	20-20 MG	M ; N ; O ; Y	N		

POLICY AGENT SUMMARY QUANTITY LIMIT

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Bonjesta	Doxylamine-Pyridoxine Tab ER 20-20 MG	20-20 MG	60	Tablets	30	DAYS			
Diclegis	Doxylamine-Pyridoxine Tab Delayed Release 10-10 MG	10-10 MG	120	Tablets	30	DAYS			

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Bonjesta	doxylamine-pyridoxine tab er	20-20 MG	FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Diclegis	doxylamine-pyridoxine tab delayed release	10-10 MG	FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Bonjesta	Doxylamine-Pyridoxine Tab ER 20-20 MG	20-20 MG	FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Diclegis	Doxylamine-Pyridoxine Tab Delayed Release 10-10 MG	10-10 MG	FlexRx Closed ; FlexRx Open ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Target Agent(s) will be approved when ALL of the following are met: 1. ONE of the following: A. The requested agent is being used to treat pregnancy related nausea or vomiting (not including hyperemesis gravidarum) **OR** B. The patient has another FDA approved indication for the requested agent **AND** 2. The prescriber has provided information 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 contraindications to the requested agent **Length of Approval:** Up to due date of pregnancy NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity Limit for the Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) is greater than the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit **OR** 3. ALL of the following: A. The requested quantity (dose) is greater than the program quantity limit **AND** B. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication **AND** C. The prescriber has provided information in support of therapy with a higher dose for the requested indication **Length of Approval**: Up to due date of pregnancy