 JOHNS HOPKINS HEALTH PLANS	Johns Hopkins Health Plans Pharmacy Public Medical Management Drug Policies	<i>Policy Number</i>	MMDP105
		<i>Effective Date</i>	07/17/2024
		<i>Approval Date</i>	07/17/2024
	<i>Subject</i> Danyelza	<i>Supersedes Date</i>	N/A
		<i>Page</i>	1 of 2

This document applies to the following Participating Organizations:

US Family Health Plan

Keywords: Danyelza

Table of Contents	Page Number
I. POLICY	1
II. POLICY CRITERIA	1
III. AUTHORIZATION PERIOD/LIMITATIONS	1
IV. EXCLUSIONS	1
V. RECOMMENDED DOSE	1
VI. CODES	1
VII. REFERENCES	2
VIII. APPROVALS	2

I. POLICY

- A. Danyelza (naxitamab-gqgk) will require prior authorization for medical benefit coverage to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.

II. POLICY CRITERIA

- A. Danyelza may be approved for patients who meet the following:
1. Documentation has been submitted showing all of the following:
 - a. Diagnosis of high-risk neuroblastoma
 - b. Patient is 1 year of age or older with relapsed or refractory disease in the bone or bone marrow
 - c. Patient has demonstrated a partial or minor response or stable disease with prior therapy
 - d. Danyelza will be used in combination with granulocyte-macrophage colony-stimulating factor (GM-CSF)

III. AUTHORIZATION PERIOD/LIMITATIONS

- A. Initial approval will be limited to 12 months of therapy
- B. Continuation of therapy may be approved in 12-month intervals with documentation showing the patient has not experienced unacceptable toxicity or disease progression while on treatment

IV. EXCLUSIONS


- A. Danyelza will not be covered for the following:
1. Any indications or uses that are not FDA-approved, or guideline-supported

V. RECOMMENDED DOSE

Please refer to the FDA-approved prescribing information, or clinical guidelines, for indication-specific dosing details.

VI. CODES

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		<i>Page</i>	2 of 2

Note: The following CPT/HCPCS codes are included below for informational purposes. Inclusion or exclusion of a CPT/HCPCS code(s) below does not signify or imply member coverage or provider reimbursement. The member's specific benefit plan determines coverage.

Medication	HCPCS/CPT Code
Injection, naxitamab-gqqk, 1 mg	J9348

VII. REFERENCES

1. Danyelza [prescribing information]. New York, NY: Y-mAbs Therapeutics, Inc.; November 2020.

VIII. APPROVALS

Signature on file at JHHP

DATE OF REVISION	SUMMARY OF CHANGE
07/17/2024	Policy creation

Review Date: 07/17/2024

Revision Date: