Clinical Policy: Aprepitant (Aponvie only)

Reference Number: PA.CP.PMN.19
Effective Date: 01/2023
Last Review Date: 01/2023

Revision Log

Description
Aprepitant (Aponvie™) is substance P/neurokinin 1 (NK1) receptor antagonist.

FDA Approved Indication(s)
Aponvie is indicated:
- For prevention of postoperative nausea and vomiting (PONV) in adults

Limitation(s) of use:
- Aponvie has not been studied for treatment of established nausea and vomiting.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of PA Health & Wellness® that Aponvie is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Prevention of Postoperative Nausea and Vomiting (must meet all)**:**

1. Request is for Aponvie, all other requests covered under PHW.PDL.085 Antiemetics-Antivertigo Agents;
2. Prescribed for the prevention of PONV;
3. Age ≥ 18 years;
4. Member is scheduled to receive surgery;
5. Failure of a 5-HT_3 receptor antagonist (*ondansetron and granisetron are preferred*) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
6. Dose does not exceed 32 mg (one vial) once.

Approval duration: 3 days (one time dose)

B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

II. Continued Therapy

A. Prevention of Postoperative Nausea and Vomiting

1. Re-authorization is not permitted. Members must meet the initial approval criteria.

Approval duration: Not applicable

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

5-HT_3: serotonin 5-hydroxytryptamine, type 3
FDA: Food and Drug Administration
NK_1: neurokinin 1
PONV: postoperative nausea and vomiting

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
5-HT_3 Serotonin Antagonists		
granisetron (Kytril®)	**Prevention of PONV*** 0.35 to 3 mg (5 to 20 mcg/kg) IV at the end of surgery	20 mcg/kg/dose
ondansetron (Zofran®, Zofran® ODT)	**Prevention of PONV** 16 mg PO given 1 hour prior to anesthesia or 4 mg IM/IV as a single dose given 30 min before end of anesthesia	PO: 16 mg/dose IV: 4 mg/dose

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.
**Off-label*

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): known hypersensitivity, concurrent use with pimozide
- Boxed warning(s): none reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Prevention of postoperative nausea and vomiting	32 mg IV prior to induction of anesthesia	32 mg

VI. Product Availability

Single-dose vial, injectable emulsion: 32 mg/4.4 mL

VII. References

1. Aponvie Prescribing Information. San Diego, CA: Heron Therapeutics, Inc.; September 2022. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/216457s000lbl.pdf. Accessed September 21, 2022.
2. Gan TJ, Belani KG, Bergese S, et al. Fourth Consensus Guidelines for the Management of Postoperative Nausea and Vomiting. Anesthesia & Analgesia: August 2020. 131 (2), 411-448.

HCPCS Codes	Description
J0185	Injection, aprepitant, 1 mg

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	01/2023	