GOLD COAST HEALTH PLAN TOTAL Care ADVANTAGE℠

TOTAL CARE ADVANTAGE PART B CLINICAL GUIDELINES

DATROWAY® *(datopotamab deruxtecan-dlnk)* for injection, for IV use

PA Criteria	Criteria Details
Description	DATROWAY® is a Trop-2-directed antibody and topoisomerase inhibitor conjugate
Covered Uses (FDA approved indication)	DATROWAY® is indicated for the treatment of: a. adult patients with locally advanced or metastatic EGFR-mutated non-small cell lung cancer (NSCLC) who have received prior EGFR-directed therapy and platinum-based chemotherapy*. b. adult patients with unresectable or metastatic hormone receptor (HR) positive, human epidermal growth factor 2 (HER2) negative (IHC 0, IHC 1+ or IHC 2+/ISH-) breast cancer who have received prior endocrine-based therapy and chemotherapy for unresectable or metastatic disease. **This indication is approved under accelerated approval based on objective response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trial.*
Dosing and Administration	**Indication:** Breast Cancer, NSCLC **Dosing Regimen:** 6 mg/kg IV infusion Q3 weeks (21-day cycle) Continue until disease progression or unacceptable toxicity. **Maximum Dose:** 540 mg* *for patients ≥ 90 kg

	Infusion Time	Post-Infusion Observation
1st infusion	90 min	1 hour
2nd infusion	30 min	1 hour
Subsequent infusions	30 min	30 min

Billing and Coding Information

10-digit NDC	11-digit NDC
65597-801-01	65597-0801-01

HCPCS Code	Description
J9011	Injection, datopotamab deruxtecan-dlnk, 1mg

CPT Procedural Codes	Description
96413	Chemotherapy IV infusion, up to one hour
96415	Chemotherapy IV infusion, additional hour*

*Used as an add-on code for every hour of infusion that is more than 30 min past the initial 1 hour

Product Availability	*Single dose vial:* 100 mg lyophilized powder for reconstitution.
Contraindications	None.

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Recommended Medical Monitoring	Datroway® has been associated with: a. Interstitial Lung Disease (ILD) and Pneumonitis b. Ocular adverse reactions (including dry eye, keratitis, blepharitis, meibomian gland dysfunction, increased lacrimation, conjunctivitis, and blurred vision) c. Stomatitis/Oral Mucositis d. Embryo-fetal Toxicity Patients should be monitored for any of these reactions. Datroway® dose may be delayed, reduced or permanently discontinued based on the severity of adverse reactions. Datroway can cause fetal harm when administered to a pregnant woman. Verify pregnancy status in females of reproductive potential prior to initiating Datroway treatment. Female patients of reproductive potential should be advised to use effective contraception during treatment with Datroway and for **seven months** after the last dose.
Approval Criteria **Breast Cancer**	a. Physician administered IV infusion; in-office or HOPD i. Cannot be self-administered b. Breast Cancer **(must meet all)**: i. Diagnosis of unresectable or metastatic breast cancer ii. Prescribed by or in consultation with an oncologist iii. Patient age ≥ 18 years iv. Documentation of HR+ disease v. Documentation of HER2- disease (IHC 0, IHC 1+ or IHC 2+/ISH-) vi. Patient received prior endocrine-based therapy *(see Appendix)* vii. Patient received prior chemotherapy for unresectable or metastatic disease (see Appendix) viii. Prescribed as single agent ix. Request meets one of the following: 1. Dose does not exceed 6 mg/kg or 540 mg total once every three weeks (21-day cycle) 2. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence)
Approval Criteria **NSCLC**	a. Physician administered IV infusion; in-office or HOPD i. Cannot be self-administered b. Non-Small Cell Lung Cancer **(must meet all)**: i. Diagnosis of locally advanced or metastatic NSCLC vii. Prescribed by or in consultation with an oncologist vii. Patient age ≥ 18 years vii. Documentation of EGFR+ disease vii. Patient received prior EGFR-directed therapy and platinum-based chemotherapy *(see Appendix)* vii. Prescribed as a single agent vii. Request meets one of the following 1. Dose does not exceed 6 mg/kg or 540 mg total once every three weeks (21-day cycle) 2. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence)

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Age Restriction	Adults ≥ 18 years old.
Coverage Duration	Initial: six months. Reauthorization: 12 months. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
Appendix	**Examples of systemic therapies for recurrent unresectable or metastatic breast cancer:** a. Albumin-bound Paclitaxel (Abraxane) b. Capecitabine (Xeloda) c. Carboplatin (Paraplatin) d. Cisplatin (Kemoplat) e. Cyclophosphamide (Frindovyx) f. Docetaxel (Taxotere) g. Doxorubicin (Adriamycin) h. Epirubicin (Ellence) i. Eribulin (Halaven) j. Gemcitabine (Gemzar) k. Ixabepilone (Ixempra) l. Liposomal doxorubicin (Doxil) m. Paclitaxel n. Vinorelbine (Navelbine) **Examples of endocrine based therapy for breast cancer:** a. Anastrozole (Arimidex) b. Exemestane (Aromasin) c. Letrozole (Femara) d. Tamoxifen **Examples of targeted EGFR therapies for NSCLC:** a. Afatinib (Gilotrif) b. Amivantamab (Rybrevant) c. Erlotinib (Tarceva) d. Osimertinib (Tagrisso) e. Sunvozertinib (Zegfrovy) **Examples of targeted EGFR therapies for NSCLC:** a. Carboplatin b. Cisplatin

STATUS	DATE REVISED	REVIEW DATE	APPROVED/REVIEWED BY	EFFECTIVE DATE
Created	9/8/2025	9/8/2025	Tamara Chinarian, PharmD, Clinical Pharmacist	N/A
Approved	N/A	11/13/2025	Pharmacy & Therapeutics (P&T) Committee	11/13/2025