Clinical Policy: Dexrazoxane (Zinecard, Totect)

Reference Number: LA.PHAR.418
Effective Date:
Last Review Date: 04.22 Coding Implications
Line of Business: Medicaid Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Dexrazoxane (Zinecard®, Totect®) is a cytoprotective agent.

FDA Approved Indications

Totect and Zinecard are indicated for reducing the incidence and severity of cardiomyopathy associated with doxorubicin in women with metastatic breast cancer who have received a cumulative doxorubicin dose of 300 mg/m^2 and will continue receiving doxorubicin to maintain tumor control.

Totect is indicated for the treatment of extravasation resulting from intravenous anthracycline chemotherapy.

Policy/Criteria

Prior Authorization is required. 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 Louisiana Healthcare Connections that Zinecard and Totect are medically necessary when the following criteria are met:

I. Initial Approval Criteria
- **A.** Doxorubicin-Induced Cardiomyopathy (must meet all):
  1. Prescribed to reduce the incidence or severity of cardiomyopathy associated with doxorubicin;
  2. Prescribed by or in consultation with an oncologist or hematologist;
  3. One of the following:
     a. Age ≥ 18 years and member has received a cumulative doxorubicin dose of ≥ 300 mg/m^2;
     b. Request is for Ph-negative ALL as part of the DFCI ALL Protocol 11-001 or 16-001 in members with an anticipated cumulative anthracycline dose ≥ 250 mg/m^2 of doxorubicin equivalent or radiation with potential impact to the heart (e.g., radiation to chest, abdomen, spine, or total body irradiation) (off-label);
     c. Request is for pediatric aggressive mature B-cell lymphomas or Hodgkin lymphoma (off-label);
     d. Request is for Wilms Tumor (nephroblastoma) and member has a planned cumulative dose of doxorubicin ≥ 150 mg/m^2 (off-label);
  4. Will be used concurrently with doxorubicin;
  5. Request meets one of the following (a or b):*

a. Dose does not exceed 10 times the dose of doxorubicin (e.g., dexrazoxane 500 mg/m^2 for member receiving doxorubicin 50 mg/m^2) given with each doxorubicin dose;
b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 12 months or duration of doxorubicin therapy, whichever is less

B. Anthracycline-Induced Extravasation (must meet all):
1. Diagnosis of anthracycline-induced extravasation;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Dose does not exceed 2,000 mg per day on days 1 and 2, and 1,000 mg on day 3.

Approval duration: 3 days

C. 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): LA.PMN.53 for Medicaid.

II. Continued Therapy

A. Doxorubicin-Induced Cardiomyopathy (must meet all):
1. Currently receiving medication via Louisiana Healthcare Connections benefit or member has previously met initial approval criteria;
2. Member continues to receive doxorubicin;
3. Member is responding positively to therapy;
4. Request meets one of the following (a or b):*
   a. Dose does not exceed 10 times the dose of doxorubicin (e.g., dexrazoxane 500 mg/m^2 for member receiving doxorubicin 50 mg/m^2) given with each doxorubicin dose;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 12 months or duration of doxorubicin therapy, whichever is less

B. Anthracycline-Induced Extravasation
1. Re-authorization is not permitted. Member must meet the initial approval criteria.

Approval duration: Not applicable

C. Other diagnoses/indications (must meet 1 or 2):
1. Currently receiving medication via Louisiana Healthcare Connections benefit and documentation supports positive response to therapy.

Approval duration: Duration of request or 6 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): LA.PMN.53 for Medicaid.

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 policy – LA.PMN.53 for Medicaid, or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ALL: acute lymphoblastic leukemia
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Zinecard: should not be used with non-anthracycline chemotherapy regimens
  - Totect: none reported
- Boxed warning(s): none reported

V. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose
dexrazoxane (Totect, Zinecard)	Doxorubicin-induced cardiomyopathy	Give dexrazoxane at a ratio of 10:1 with the doxorubicin dose as an IV infusion over 15 minutes and within 30 minutes before doxorubicin is given.	Not applicable
dexrazoxane (Totect)	Anthracycline-induced extravasation	Day 1: 1,000 mg/m^2 Day 2: 1,000 mg/m^2 Day 3: 500 mg/m^2 Give Totect as an IV infusion over 1-2 hours and within 6 hours of extravasation. Treatment on days 2 and 3 should start at the same hour (+/- 3 hours) as day 1.	Day 1: 2,000 mg Day 2: 2,000 mg Day 3: 1,000 mg

VI. Product Availability

Drug Name	Availability
dexrazoxane (Zinecard)	Single-dose vial, IV powder for solution: 250 mg, 500 mg

Drug Name	Availability
dexrazoxane (Totect)	Single-dose vial, IV powder for solution: 500 mg

VII. References

1. Zinecard Prescribing Information. New York, NY: Pharmacia & Upjohn Co; October 2016. Available at: http://labeling.pfizer.com/ShowLabeling.aspx?format=PDF&id=514 . Accessed February 14, 2022.
2. Totect Prescribing Information. Yardville, PA: Clinigen, Inc; November 2020. Available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=b098c7f5-07a9-49a3-8e8a-f8adda671eca&audience=consumer. Accessed February 14, 2022.
3. American Society of Clinical Oncology 2008 Clinical Practice Guideline Update: Use of Chemotherapy and Radiation Therapy Protectants. Available at: http://ascopubs.org/doi/pdf/10.1200/JCO.2008.17.2627. J Clin Oncol; 27:127-145.
4. Choi HS, Park ES, Kang HJ, et al. Dexrazoxane for preventing anthracycline cardiotoxicity in children with solid tumors. J Korean Med Sci. 2010;25(9):1336-42.
5. Asselin BL, Devidas M, Chen L, et al. Cardioprotection and Safety of Dexrazoxane in Patients Treated for Newly Diagnosed T-Cell Acute Lymphoblastic Leukemia or Advanced-Stage Lymphoblastic Non-Hodgkin Lymphoma: A Report of the Children's Oncology Group Randomized Trial Pediatric Oncology Group 9404. J Clin Oncol. 2016;34(8):854-62.
6. Dexrazoxane. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: https://nccn.org/. Accessed February 14, 2022.
7. National Comprehensive Cancer Network. Pediatric Aggressive Mature B-Cell Lymphomas Version 2.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/ped_b-cell.pdf. Accessed February 14, 2022.
8. National Comprehensive Cancer Network. Pediatric Acute Lymphoblastic Leukemia Version 1.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/ped_all.pdf. Accessed February 14, 2022.
9. National Comprehensive Cancer Network. Pediatric Hodgkin Lymphoma Version 3.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/ped_hodgkin.pdf. Accessed February 14, 2022.
10. National Comprehensive Cancer Network. Wilms Tumor (Nephroblastoma) Version 2.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/wilms_tumor.pdf. Accessed February 14, 2022.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J1190	Injection, dexrazoxane, 250 mg

Dexrazoxane

Reviews, Revisions, and Approvals	Date	LDH Approval Date
Converted corporate to local policy.	04.22	

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. LHCC retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom LHCC has no control or right of control. Providers are not agents or employees of LHCC.

Dexrazoxane