RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Clinical Policy Title:	sacituzumab govitecan-hziy
Policy Number:	RxA.634
Drug(s) Applied:	TRODELVY®
Original Policy Date:	09/14/2020
Last Review Date:	09/14/2020
Line of Business Policy Applies to:	All lines of business

Background

TRODELVY® is a Trop-2-directed antibody and topoisomerase inhibitor conjugate indicated for the treatment of adult patients with metastatic triple-negative breast cancer (mTNBC) who have received at least two prior therapies for metastatic disease.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
sacituzumab govitecan-hziy (TRODELVY®)	metastatic triple-negative breast cancer (mTNBC)	10 mg/kg once weekly on Days 1 and 8 of continuous 21-day treatment cycles until disease progression or unacceptable toxicity	10 mg/kg

Dosage Forms

- IV for injection: 180 mg lyophilized powder in single-dose vials for reconstitution.

Clinical Policy

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

I. Initial Approval Criteria

A. Metastatic Triple-Negative Breast Cancer

1. Member is ≥ 18 years of age;
2. Diagnosis of metastatic triple-negative breast cancer (mTNBC);
3. Prescribed by or in consultation with an oncologist;
4. Received at least two prior therapies for metastatic disease;
5. ECOG performance status of 0 or 1;
6. Dose does not exceed 10 mg/kg

Approval Duration:
Commercial: 8 weeks
Medicaid: 8 weeks

II. Continued Therapy Approval

A. Metastatic Triple-Negative Breast Cancer

1. Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. Dose does not exceed 10 mg/kg

Approval Duration
Commercial: 8 weeks
Medicaid: 8 weeks

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
mTNBC - metastatic triple-negative breast cancer

APPENDIX B: Therapeutic Alternatives

Drug Name	Daily Dose	Dose Limit/Maximum Dose
fluorouracil (Adrucil®)	500 mg/m2 or 600 mg/m2 IV on days 1 and 8, as a component of a cyclophosphamide-based multidrug regimen, every 28 days for 6 cycles	See dosing regimen
epirubicin (Ellence®)	75 mg/m2 IV on day 1 in combination with cyclophosphamide 600 mg/m2 IV on day 1, every 3 weeks for 6 cycles 50 mg/m2 IV on days 1 and 8 in combination with cyclophosphamide 500 mg/m2 IV on days 1 and 8, plus fluorouracil 400 mg/m2 IV on days 1 and 8, every 3 to 4 weeks depending on patient recovery	See dosing regimen
cyclophosphamide IV	600 mg/m2 IV on day 1 in combination with epirubicin 75 mg/m2 IV on day 1, every 3 weeks for 6 cycles 500 mg/m2 IV on days 1 and 8 in combination with epirubicin 50 mg/m2 IV on days 1 and 8, plus fluorouracil 400 mg/m2 IV on days 1 and 8, every 3 to 4 weeks depending on patient recovery	See dosing regimen

paclitaxel (Abraxane®)	100 mg/m2 IV over 30 minutes on days 1, 8, and 15, in combination with atezolizumab 840 mg IV over 60 minutes on days 1 and 15, repeated every 28 days until disease progression or unacceptable toxicity	See dosing regimen
atezolizumab (Tecentriq®)	840 mg IV over 60 minutes on days 1 and 15, followed by nab-paclitaxel (100 mg/m2 IV over 30 minutes on days 1, 8, and 15), repeated every 28 days until disease progression or unacceptable toxicity	See dosing regimen

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Severe hypersensitivity reaction to TRODELVY

- Boxed Warning(s):
  - Severe Neutropenia - Withhold TRODELVY for absolute neutrophil count below 1500/mm3 or neutropenic fever. Monitor blood cell counts periodically during treatment. Consider G-CSF for secondary prophylaxis. Initiate anti-infective treatment in patients with febrile neutropenia without delay.
  - Severe Diarrhea – Monitor patients with diarrhea and give fluid and electrolytes as needed. Administer atropine, if not contraindicated, for early diarrhea of any severity. At the onset of late diarrhea, evaluate for infectious causes and, if negative, promptly initiate loperamide. If severe diarrhea occurs, withhold TRODELVY until resolved to ≤ Grade 1 and reduce subsequent doses.

APPENDIX D: General Information

- Triple-negative breast cancer (TNBC) tumors do not carry receptors for estrogen, progesterone, or human epidermal growth factor (HER2). It is a more aggressive form of breast cancer that is harder to treat and for which there are fewer approved medicines.

References

1. TRODELVY Prescribing Information. Morris Plains, NJ: Immunomedics; Issued April 2020. Available at https://www.trodelvy.com/. Accessed July 1, 2020
2. FDA. https://www.fda.gov/news-events/press-announcements/fda-approves-new-therapy-triple-negative-breast-cancer-has-spread-not-responded-other-treatments. Accessed July 1, 2020
3. Clinical Pharmacology [database online] powered by ClinicalKey. Tampa, FL: Elsevier, 2020. Accessed with subscription at: http://www.clinicalkey.com. Accessed July 1, 2020.
4. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed June 24, 2020.

Review/Revision History	Review/Revised Date	P&T Approval Date

Policy established.	9/14/2020	09/14/2020