Clinical Policy Title:	Chemotherapy Not Otherwise Specified
Policy Number:	RxA.671
Drug(s) Applied:	Too numerous to list
Original Policy Date:	03/09/2021
Last Review Date:	03/09/2021
Line of Business Policy Applies to:	All lines of business

Background

This policy provides information regarding chemotherapy product(s), approved uses, and criteria for approval. This policy should not be used if there is a drug-specific policy available for a chemotherapy product. This policy does not apply to radiopharmaceuticals or supportive care therapies that may be concomitantly given during chemotherapy.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Where such mandates apply, state language supersedes language in this policy.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
Too numerous to list	Indications for specific chemotherapy products are available in FDA prescribing information or other compendial references.	N/A	N/A

Dosage Forms

- Too numerous to list

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. All Cancer Indications (must meet all):

1. Member has a documented clinical diagnosis for which the chemotherapeutic product is indicated for based on FDA prescribing information or evidence-based guidelines;
2. Prescribed by or in consultation with a hematologist or oncologist;
3. Member is of the appropriate age for the prescribed chemotherapy product and regimen (if applicable) based on FDA prescribing information or evidence-based guidelines;
4. Prescribed chemotherapy product and regimen (if applicable) for the specified cancer diagnosis is (a, b, c, or d):
   a. FDA-approved;
   b. Recognized in the National Comprehensive Cancer Network (NCCN) Drug Information and Biologics

Compendium with categories of evidence and consensus of 1 or 2A (*see Appendix D*);
   c. Recognized in the American Society of Clinical Oncology (ASCO) with a strength of recommendation of strong or moderate (*see Appendix D*);
   d. If prescribed chemotherapy product and regimen (if applicable) is not FDA-approved or recognized in the National Comprehensive Cancer Network (NCCN) Drug Information and Biologics Compendium, criteria for off-label use outlined in policy RxA.601 must be met in addition to criteria listed here;
5. Member has tried and failed at least two (2) preferred drug formulary products that are considered standards of care according to NCCN or ASCO guidelines (based on cancer type, staging, pharmacogenomics, drug mechanism of action, previously tried therapies), at maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced (If only one preferred product exists, member only need to demonstrate failure of an adequate trial of that drug);
   a. If chemotherapy product requested is non-formulary, criteria for a formulary exception outlined in policy RxA.137 must be met in addition to the criteria listed here;
   b. If members have clinical contraindication(s) to NCCN or ASCO recommended chemotherapy regimens, the provider should submit clinical documentation explaining the contraindication;
6. Member has no contraindications to the prescribed chemotherapy product per the product information label;
7. If applicable, prescriber has taken necessary measures to minimize any risk(s) associated with a boxed warning and/or contraindications in the product information label;
8. Dose does not exceed FDA prescribing guidelines or dosing is supported by evidence-based guidelines or peer-reviewed literature for the relevant off-label use.

Approval Duration
Commercial: Duration of request or 6 months (whichever is less)
Medicaid: Duration of request or 6 months (whichever is less)

II. Continued Therapy Approval

A. All Cancer Indications (must meet all):
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 (e.g., tumor stabilization, lack of tumor progression);
3. Prescribed chemotherapy product and regimen (if applicable) for the specified cancer diagnosis is (a, b, c, or d):
   a. FDA-approved;
   b. Recognized in the National Comprehensive Cancer Network (NCCN) Drug Information and Biologics Compendium with categories of evidence and consensus of 1 or 2A (*see Appendix D*);
   c. Recognized in the American Society of Clinical Oncology (ASCO) with a strength of recommendation of strong or moderate (*see Appendix D*);
   d. If prescribed chemotherapy product and/or regimen is not FDA-approved or recognized in the National Comprehensive Cancer Network (NCCN) Drug Information and Biologics Compendium, criteria for off-label use outlined in policy RxA.601 must be met;
4. If request is for a dose increase (quantity or frequency), the member has been titrated up from a lower dose with documentation of partial improvement, dose does not exceed FDA prescribing guidelines or dosing is supported by evidence-based guidelines or peer-reviewed literature for the relevant off-label use.

Approval Duration
Commercial: Duration of request or 12 months (whichever is less)
Medicaid: Duration of request or 12 months (whichever is less)

III. Appendices

APPENDIX A: Abbreviation/Acronym Key

ASCO: American Society of Clinical Oncology
FDA: Food and Drug Administration
NCCN: National Comprehensive Cancer Network

APPENDIX B: Therapeutic Alternatives

- Varies by chemotherapy product

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Hypersensitivity to any component of the chemotherapy product
  - Refer to the specific chemotherapy product prescribing information or compendial references for other contraindications.

- Boxed Warning(s):
  - Varies by chemotherapy product

APPENDIX D: General Information

- NCCN Categories of Evidence and Consensus (all recommendations are category 2A unless otherwise indicated):
  - Category 1: Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
  - Category 2A: Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
  - Category 2B: Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.
  - Category 3: Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate

- ASCO Strengths of Recommendation:
  - Strong: There is high confidence that the recommendation reflects best practice. This is based on:
    - Strong evidence for a true net effect (e.g., benefits exceed harms);
    - Consistent results, with no or minor exceptions;
    - Minor or no concerns about study quality; and/or
    - The extent of panelists' agreement.

    Other compelling considerations (discussed in the guideline's literature review and analyses) may also warrant a strong recommendation.
  - Moderate: There is moderate confidence that the recommendation reflects best practice. This is based on:
    - Good evidence for a true net effect (e.g., benefits exceed harms);
    - Consistent results, with minor and/or few exceptions;
    - Minor and/or few concerns about study quality; and/or
    - The extent of panelists' agreement.

    Other compelling considerations (discussed in the guideline's literature review and analyses) may also w arrant a moderate recommendation
  - Weak: There is some confidence that the recommendation offers the best current guidance for practice. This is based on:

- Limited evidence for a true net effect (e.g., benefits exceed harms);
- Consistent results, but with important exceptions;
- Concerns about study quality; and/or
- The extent of panelists' agreement.

Other considerations (discussed in the guideline's literature review and analyses) may also warrant a weak recommendation

References

1. Food and Drug Administration. Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices. January 2009. Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/good-reprint-practices-distribution-medical-journal-articles-and-medical-or-scientific-reference. Accessed February 1, 2021.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed February 1, 2021.
3. ASCO.org (2021). Guidelines, tools, & resources. Available at: https://www.asco.org/research-guidelines/quality-guidelines/guidelines. Accessed February 1, 2021.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	02/01/2021	03/09/2021