Optum Care Administration Guideline – General Pharmacy Utilization Management

Topic:	**General Pharmacy Utilization Management - CGP**		
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Overview:

This guideline addresses the need for utilization review of pharmaceutical treatment services and the governance of medical necessity determinations. Rather than provide specific aspects of all clinical situations, this policy is intended to remain broad in its context but provide practical guidance on how pharmaceutical medical necessity is defined and decisioned. The intent of the guideline is that it be adopted and utilized across the OptumCare organization. It has been designed to be utilized across all lines of business and to be payor agnostic allowing applicability with all contracted health plans.

The goal of OptumCare utilization review is four-fold:

- Provide patient-centered care through timely, standardized, prior authorization experiences system-wide
- Provide clinician satisfaction through reduction in administrative tasks related to prior authorization through standardization and transparency of evidence-based criteria
- Provide high quality outcomes through clinical decision support based on clinically valid evidence-based medicine
- Provide cost-effective care through medical error minimization and reduction in variation of care

OptumCare, as a delegated entity, is required to perform utilization management activities such as prior authorization to determine medical necessity for certain outpatient injectable drugs for which they have contractual obligation and/or carry delegated risk. These determinations are required to be reviewed within the scope of the hierarchy of review for clinical decision making. The hierarchy of review is dictated by federal and state law, Medicare and Medicaid policy, contract conditions, and health plan coverage policies. OptumCare makes every effort to ensure that the hierarchy of review is considered when writing individual drug criteria guidelines. In general, the hierarchy of review is as follows:

- Federal statute, Regulations, Rules and Policies including, but not limited to National Coverage Determinations, Local Coverage Determinations and Articles, CMS Benefit Policy Manuals,
- State Statutes, Regulations, Rules, and Policies including those that regulate insurance coverage and Medicaid
- Health Plan pharmacy guidelines, policies and procedures for which adherence is contractually required
- Medical necessity guidelines such as MCG or InterQual

- OptumCare guidelines and policies as developed and approved by the National Value and Therapeutics Committee

Drugs Requiring Prior Authorization

OptumCare will require review of following for prior authorization:

- Outpatient Injectable drugs used to treat cancer – see section “Review of chemotherapy agents”
- Outpatient therapeutic radiopharmaceuticals
- Outpatient specialty medications, including supportive therapies such as anti-emetics
- Outpatient medications that are billed under not otherwise classified HCPCS codes (i.e. J3490, J3590, J9999, C9399, J7999, etc.)
- CMS assigns drugs with NOC codes to permanent codes on an ongoing basis. Drugs with newly assigned codes from CMS will require prior authorization.

OptumCare does not require prior authorization on:

- Drugs used as part of an inpatient admission
- Drugs used in health emergencies, antidotes, or for reversal agents used for overdose

A complete list of drugs requiring authorization is updated routinely and is located at the following URL: https://marketingcloud.optum.com/content/rxcaresolutions/cgp/en.html

Examples of situations in which a prior authorization may be denied:

- Drugs that are not covered as benefits under the members health plan
- Drugs determined not to be medically necessary after utilization review
- Drugs and immunizations that are excluded from Medicare Part B benefits
- Drugs that are listed by compendia as not medically accepted:
    - Category 3 in NCCN
    - Class III in DrugDex
    - “Not supported” in Clinical Pharmacology, or
    - “Use: Unsupported” in Lexi-Drugs

Determination of Medical Necessity

Prior authorization is a process used by OptumCare to help improve the healthcare experience, clinical outcomes, and the cost of care for our patients. Each prior authorization is reviewed for medical necessity to ensure that the request is within the acceptable scope of medical practice and likely to result in clinical benefit, minimal toxicity, maximum safety, and ensure cost effectiveness. Medical necessity indicates the drug is reasonable and necessary for the diagnosis or treatment of illness or injury and will be administered according to accepted standard of medical practice. Evaluation of medical necessity includes assessment of the drug for an intended indication, dosage, duration, frequency, safety, and cost-effectiveness. OptumCare may utilize automation platforms, medical reviewers, or a combination to review and make determinations. The reviews may be performed against coverage guidelines such as national coverage determinations (NCDs), local coverage determinations (LCDs), Medicare benefit policy manuals,

specific Health Plan criteria and policies, and criteria specifically developed by OptumCare. Criteria developed by OptumCare is based on objective, evidence-based literature, and nationally accepted guidelines approved through a national committee with multi-disciplinary membership.

Review of Medicare Part B vs Part D

Medications covered under Medicare can be classified into two broad coverage categories: those covered under the outpatient pharmacy benefit (aka Part D- Medicare) (a written prescription is processed and dispensed at a local or mail order pharmacy for the patient to self-administer at home) and those covered under the medical benefit (aka Part B – Medicare) (usually administered by a healthcare professional during a physician office or clinic visit or as part of an outpatient procedure). Drugs covered under a medical benefit are usually limited to drugs or biologicals administered by infusion or injection. However, if a drug is self-administered by injection (e.g. Imitrex, insulin) they are not covered as medical (Part B) benefits. The place where the drug is administered also dictates how the medication is covered (i.e. inpatient stay vs skilled-nursing facility vs patient's home). Please refer individual CMS LCD/LCA Self-Administered Determination Guideline Articles for further details: https://www.cms.gov/medicare-coverage-database/reports/sad-exclusion-list-report.aspx.

OptumCare Recommended Products

OptumCare reviews drugs in the same class that are acceptable therapeutic equivalents for certain indications and determines recommended products based on efficacy, safety, and cost-effectiveness. These drugs are reviewed periodically by a multidisciplinary national committee and are recommended in the automation platforms and other value initiatives. These drugs will be listed as recommended in the platform and their use will be encouraged. Utilization management determinations for recommended product decisions will be governed by the applicable market hierarchy. OptumCare may be contractually obligated to abide by Health Plan step therapy programs as well. Therefore, denials may be rendered if the prior authorization request is not in compliance with these programs.

Health Plan Step Therapy Requirements			
UHC Preferred	Anthem Preferred	**OptumCare Recommended Product**	**OptumCare Not Recommended**
gemcitabine	-	gemcitabine	Infugem
leucovorin	-	leucovorin calcium	Fusilev Khapzory
Neulasta **Ziextenzo**	Neulasta Neulasta Onpro Udenyca	Biosimilar recommended Fulphila Udenyca Ziextenzo Nyvepria	Neulasta
Zarxio	Zarxio	Biosimilar recommended Nivestym Zarxio Granix Releuko	Neupogen
Mvasi Zirabev	-	Biosimilar recommended Mvasi Zirabev	Avastin
Retacrit	-	Biosimilar recommended Retacrit	Procrit Aranesp
Truxima **Ruxience**	-	Biosimilar recommended Truxima Ruxience Riabni	Rituxan
Kanjinti **Trazimera**	-	Biosimilar recommended Herzuma Kanjinti Ogivri Ontruzant Trazimera	Herceptin Herceptin Hylecta
-	-	zoledronic acid	Prolia, Xgeva
Aloxi **Emend** **granisetron** **ondansetron**	-	Aloxi Emend Granisteron Ondansetron	Akynzeo Cinvanti Sustol

Review of chemotherapy agents

In some markets, prior authorization for cancer treatment may be managed by an electronic prior authorization and notification tool.

The prior authorization and notification tool supports automated review and approval of chemotherapy regimens, radiopharmaceuticals, and supportive care drugs. This reduces administrative burden on physicians and allows patients to receive safe, effective, treatment that produces quality outcomes and improved costs for all patients. Prior authorization of chemotherapy regimens is conducted in accordance with the support of evidenced based medicine with a foundation in the National Comprehensive Cancer Network Guidelines. The literature for each type of cancer treatment is further reviewed and the regimens that are substantiated with the best outcome and safety profiles are selected to be reviewed for cost-effectiveness. The best regimens are then chosen to be pathway regimens.

In general, the following chemotherapy drugs will require authorization:

- Injectable chemotherapy drugs (J9000 - J9999)
- Leucovorin (J0640) and Levoleucovorin (J0641/J0642)
- Injectable chemotherapy drugs that have a Q code
- Injectable chemotherapy drugs that have not yet received an assigned code and will be billed under a miscellaneous Healthcare Common Procedure Coding System (HCPCS) code will require prior authorization
- Therapeutic radiopharmaceuticals (A9590, A9513, A9606, A9699)

Supportive therapies such as colony-stimulating factors, and bone-modifying agents:

- Filgrastim, peg-filgrastim and biosimilar agents
- Denosumab
- Anti-emetics

A regularly update list of drug can be found here: located at the following URL: https://marketingcloud.optum.com/content/rxcaresolutions/cgp/en.html.

OptumCare recognizes indications and uses of injectable oncology medications, including supportive therapies and radiopharmaceuticals to be proven and medically necessary if they are listed in the NCCN Drugs and Biologics Compendium with a category of evidence of 1, or 2A. Category of evidence of 3 is considered unproven and not medically necessary and will be denied by OptumCare. Regimens that are labelled as category 2B will be reviewed under the necessary hierarchy. The off-label section (50.4.5.C) of the CMS Medical Benefits Policy Manual Publication No. 100-02 will be used to medically review any such requests.

OptumCare recognizes that chemotherapy agents for individuals under 19 years (pediatrics) are received under national pediatric protocols with similar framework to NCCN guidelines and will review these requests under the specified protocol.

Off-label usage

Cancer therapies are constantly emerging and as such, the process for full adoption by guidelines and standard practice may lag behind the cutting edge of medical care. Off-label use of chemotherapy drugs will be reviewed in accordance with Section 50.4.5 of Chapter 15 of the

Medical Benefits Policy Manual Publication No. 100-02.[1] The requested medications must be used in a regimen that is considered medically accepted as defined:

1. Indication is a Category 1 or 2A in NCCN, or Class I, Class IIa, or Class IIb in DrugDex; or,

2. Narrative text in AHFS-DI or Clinical Pharmacology is supportive, or

3. Indication is listed in Lexi-Drugs as "Use: Off-Label" and rated as "Evidence Level A"

Alternatively, prior authorization requests may be reviewed based on clinical research that has been published in peer-reviewed medical literature. Peer-reviewed medical literature does not include:

- In-house publications of entities whose business relates to the manufacture, sale, or distribution of pharmaceutical products
- Abstracts (including meeting abstracts)

Peer-reviewed literature should come from one of the following sources and appearing in the regular editions of the following publications (supplement editions privately funded by parties with a vested interest in the recommendations of the authors should be excluded from consideration):

- American Journal of Medicine;
- Annals of Internal Medicine;
- Annals of Oncology;
- Annals of Surgical Oncology;
- Biology of Blood and Marrow Transplantation;
- Blood;
- Bone Marrow Transplantation;
- British Journal of Cancer;
- British Journal of Hematology;
- British Medical Journal;
- Cancer;
- Clinical Cancer Research;
- Drugs;
- European Journal of Cancer (formerly the European Journal of Cancer and Clinical Oncology);
- Gynecologic Oncology;
- International Journal of Radiation, Oncology, Biology, and Physics;
- The Journal of the American Medical Association;
- Journal of Clinical Oncology;
- Journal of the National Cancer Institute;
- Journal of the National Comprehensive Cancer Network (NCCN);
- Journal of Urology;
- Lancet;
- Lancet Oncology;
- Leukemia;
- The New England Journal of Medicine; or

- Radiation Oncology

Reviews based on peer-reviewed literature will consider the following elements:

- Whether the clinical characteristics of the beneficiary and the cancer are adequately represented in the published evidence.
- Whether the administered chemotherapy regimen is adequately represented in the published evidence.
- Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients.
- Whether the study is appropriate to address the clinical question. The contractor will consider:
    - whether the experimental design, in light of the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover.);
    - that non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs; and,
    - that case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.

Review of Drugs that are Experimental and Investigational

Some Certificates of Coverage allow for members to receive coverage of experimental/investigational or unproven treatments for life-threatening illnesses under certain conditions. Furthermore, OptumCare may not be a delegated entity of the member's Health Plan to perform utilization review of experimental and investigational (E&I) services or drugs. Some examples that might be considered as E&I include, but are not limited to:

- Drugs not FDA approved for use in the US marketplace
- Drugs requested to be used in off-label situations that do not meet the criteria listed above (see off -label usage section),
- Drugs that are part of a clinical trial for an indication that is not FDA approved
- Drugs that have no compendial or literature dosing reference for a matched indication

The reviewer is permitted to use their knowledge of current medical and/or pharmaceutical practice in making such determination if a request can be considered E&I. Compendia, literature, clinical trial registries, and health plan benefit documents may be used when determining such cases.

If a drug is found to be E&I, OptumCare or Optum may need to refer to the member's specific Health Plan for guidance on appropriate handling of such requests. Some states may mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. State statutes may also mandate usage of other compendial resources.

Where such requirements apply, they would supersede this policy as outlined by the hierarchy of review.

If OptumCare is not delegated for E&I determinations:

- The requests will need to be withdrawn and submitted to the appropriate Health Plan
- A denial cannot be rendered to support compassionate use applications

Drug Dosage, Frequency and Route of Administration

The drug dosage, frequency, and route of administration may be considered when reviewing prior authorization requests. Approval may be given when the following criteria are met:

- The drug dosage, frequency, and route of administration for the treatment indication is supported by one or more of the following:
    - Approved drug labelling/package insert
    - Medicare recognized compendia:
        - American Hospital Formulary Service-Drug Information (AHFS-DI)
        - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
        - Micromedex DrugDex
        - Clinical Pharmacology
        - Lexi-Drugs
    - Dose, frequency, and route of administration is supported by published study methodology from a major scientific or medical peer-reviewed journal article showing safety and efficacy for the proposed indication
- OptumCare may utilize specific Health Plan criteria, dose rounding policies, or CMS medically unlikely edits to determine if the prior authorization request represents over-utilization, falls within acceptable utilization parameters, and determine maximum dose approvals.

Document History

- Initial Draft 5/29/20
- Approved by National V&T Committee 8/12/2020
- Revised 8/28/20 – specialty drug review removed to separate policy; drug table updated with new drugs
- Revised 11/17/20 – updates to include URL for list of drugs and changes to recommended drugs table
- Revised 1/22/20 – updates to recommended drug table to include Nyvepria, pegfilgrastim-apgf and Riabni, rituximab-arrx
- Approved by National V&T Committee 3/24/2022

References

1.Centers for Medicare & Medicaid Services. Medicare Benefit Policy Manual. Chapter 15 – Covered Medical and Other Health Services. Publication No. 100-02.

https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf. Revised July 12, 2019. Accessed November 13, 2020.

2.The NCCN Drugs and Biologics Compendium (NCCN Compendium®). http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed November 13, 2020.

3.The NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). https://www.nccn.org/professionals/physician_gls/default.aspx. Accessed November 13, 2020.