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Medication Prior Authorization Form

Oncology Coverage Policy

Policy Number: 1078

Policy History			
Approve Date:	08/01/2018	Effective Date:	08/01/2018
Revised/Reviewed Date:	02/01/2020, 04/28/2021		

Preauthorization	
All Plans	Benefit plans vary in coverage and some plans may not provide coverage for certain service(s) listed in this policy. Decisions for authorization are subject to all terms and conditions of the applicable benefit plan, including specific exclusions and limitations as well as applicable state and/or federal laws. Please review the benefit plan descriptions for details. We utilize a combination of MCG and internally developed evidence-based clinical guidelines to support our prior authorization work. All internally developed prior authorization guidelines follow a rigorous process including, but not limited to, review by clinical pharmacist, clinical nurse manager, Chief Medical Officer, independent 3rd party physician review agency and Health Tradition's Medical Advisory Committee. Prior authorization guidelines are reviewed at least annually, or when there are significant labeling changes made by FDA or peer-reviewed clinical outcomes (via Cochrane or Hayes).

Policy

Indications of Coverage

This framework is used to assist in making coverage determinations using nationally accepted guidelines (NCCN) that lend towards best outcomes, both in efficacy and safety, but also least invasive and cost-effective which is consistent with Health Tradition policy language. This policy and referenced guidelines are not used to direct care, but to determine if requested therapies meets coverage criteria. Health Tradition and INTERLINK do not direct care.

For a coverage determination to be made, all treatments for cancer shall be reviewed by INTERLINK following the NCCN-driven CVP tool. Coverage is NOT ensured unless INTERLINK reviews the chosen treatment regimen. INTERLINK will engage the oncology provider and make their best attempt to engage the member in order to make a person-centered, evidence-based recommendation for coverage of an agreed upon treatment regimen that is most effective, safest, lowest cost and least invasive.

I. Concordance is achieved when requested treatment regimen is on the Clear Value Pathway (CVP) level 2A or higher.
   A. Concordance is a level which results in a recommendation to Health Tradition to consider for coverage.
   B. All coverage determinations are made by Health Tradition.
   C. All treatment options considered include, but are not limited to surgical, chemotherapy, hormonal therapy, immunotherapy, associated supportive care and radiotherapy options.

II. Any requested treatment regimen lower than 2A or off-label is non-concordant. Any request to consider non-concordant recommendations for coverage require the following:
   A. Include at least two Phase 3 clinical trials which must be from separate researchers and institutions.
      i. These trials need to meet statistical criteria that result in a level of confidence that stated results are reliable and reproduceable and clinically relevant.
   B. For off-label requests that fail to satisfy the above, consider offering a clinical trial as a final option for treatment coverage.
      i. Refer to policy on Wisconsin Mandate for coverage of Clinical Trials
      ii. For clinical trial offers and when prognosis is poor, encourage to cover palliative care consult and palliative care.
   C. If NO to A. and B., and for cases for which there are unique circumstances that support an off-pathway treatment that would otherwise be denied, the Interlink Medical Director or Associate Medical Director shall have a peer-to-peer review with the treating oncologist to determine if extenuating circumstances support the requested regimen.

III. Use of genetic testing
   A. Genetic testing will be reviewed for medical appropriateness.
      i. Genetic testing should be used to identify a known, evidence-based mutation and not result in a random use of testing to search for potential therapies, AND
      ii. No therapy will be considered for coverage by the identification of mutations alone but require at least two controlled studies that support the use of those targeted therapies as evidenced by clinically relevant outcomes of overall survival and/or PFS.
      iii. If evidence is lacking to support the use of a therapy for an identified mutation, then the resultant genetic test results can be used ONLY for identifying an appropriate clinical trial.
   B. The use of multi-marker tumor panels is covered for:
      i. Newly diagnosed stage IV non-small cell lung cancer OR
      ii. New diagnosis of cancer of unknown origin
   C. Whole genome sequencing is not a covered benefit for the use in determining oncology therapies (unless reviewed and approved by CancerCARE and/or Health Tradition Review Panel)

IV. Biosimilars
   A. When an FDA approved biosimilar is available in the marketplace, per cost-effectiveness language in policy, the biosimilar will be recommended for approval and NOT the biologic reference product.

Any deviation from the above requires prior authorization.

Definitions

Clear Value Pathway (CVP) - McKesson's NCCN-based guidelines that drive lowest treatment costs with no observable differences in overall survival and lowest rate of chemotherapy-related hospital admissions.

Clinical trial refers to NCCN registered clinical trials to be considered for coverage, per policy language, in the event other regimens are not approved for coverage.

Concordance is defined as a treatment course that is mutually agreed upon by the oncologist, member and INTERLINK care representative that is recommended to the Trust, by INTERLINK, for consideration coverage.

Emergent reviews will be completed within 24 hours

Non-concordant is defined as not meeting coverage criteria and recommended for coverage by Health

Tradition.

Off pathway refers to CVP levels below 2A.

Off-label refers to non-FDA approved therapies or non-indicated therapies for the specified condition.

On pathway refers to CVP levels 2A and above.

PFS - progression free survival

Retrospective reviews will be completed within 30 days of receipt.

Routine reviews will be completed within 15 days of receipt.

Urgent reviews will be completed within 72 hours –Urgent is defined as "any claim for medical care or treatment with respect to which the application of the time periods for making non urgent care determinations: 1. Could seriously jeopardize the life or health of the claimant or the ability of the claimant to regain maximum function or; 2. In the opinion of a physician with knowledge of the claimant's medical condition, would subject the claimant to severe pain that cannot be adequately managed without the care of treatment that is the subject of the claim."

References

The above policy is based on the following references:

1. NCCN
2. ASCO
3. eDossier from AMCP
4. FDA
5. Evidex
6. AHFS
7. ICER