

Comments
Cytogenetic Studies
PATH 027

1. Comment

The policy does a good job of including malignant diagnoses but, as you know, cytogenetic studies may be performed in an attempt to exclude malignancy. In those cases, the final diagnosis may be benign, so I would like to offer the following additional ICD-9 codes under Acquired (cancer) Chromosome Studies:

273.1 Monoclonal gammopathy
288.50-288.59 instead of just 288.59
288.60-288.69 instead of just 288.69
285.0-285.9
281.0-281.9
287.5

Myelodysplastic syndrome, for example, may present as chronic macrocytic anemia with normal vitamin B12 and folate levels. A bone marrow biopsy may be performed, cytogenetic studies may be normal, and the final diagnosis may be macrocytic anemia, with no obvious etiology.

Patients may present with other chronic cytopenias of one sort or another and cytogenetic studies may help to diagnose or exclude a hypoplastic acute myeloid leukemia. The final diagnosis may be hypocellular bone marrow with myeloid hypoplasia, again, with no obvious etiology.

Response

We have added the diagnosis codes listed above based on the justification provided.

2. Comment

Could you please tell me why the following ICD9 codes 285.22, 285.8, 285.29, 285.9, 287.39 and 287.4 do not qualify for medical necessity for CPT code 88237 by WPS?

Response

We rely on medical literature, expert advice that is submitted to us to support coverage. If that is not forthcoming it will not necessarily then be part of the policy. We have added the code range 285.0-285.9 to the policy based on other comments received. We have also added 287.39. ICD-9 code 287.4, Secondary thrombocytopenia, describes conditions secondary to drugs or blood transfusions and it would be unlikely cytogenetic studies would be medically necessary in these instances.

3. Comment

The NCD/publication number 100-3, manual section 190.3 added Myelodysplasia as a covered diagnosis for cytogenetic testing CPT codes 88230 through 88299 in July 16, 1998. Your LCD only lists 238.74 myelodysplastic syndrome with 5q deletion. This is the rarest of all the MDS conditions. I spoke with the hematopathologist here and was told that you would perform cytogenetic testing on any MDS patient to further diagnosis the specific condition of the patient for treatment.

Our prior intermediary had all MDS codes listed in their policy of acceptable codes: 238.71, 238.72, 238.73, 238.74, 238.75 and 238.76. Please review your policy and have the additional codes added to your local policy to be consistent with the national policy as well as to afford the patient proper diagnosis and treatment.

Response

ICD-9 codes 238.71 – 238.79 are in the policy draft.

4. Comment

I have read over the policy and have one minor comment of my own for consideration. On page 2 under Discussion the second paragraph describes suitable specimens for cytogenetic testing. I believe it should also include fixed, paraffin embedded tissue and cytology specimens as choice for FISH testing. You can go to this link to the Mayo Clinic Laboratories and look up specimen requirements for FISH testing for more information:

Response

The statement “fixed, paraffin embedded tissue and cytology specimens” has been added to this section of the policy.

5. Comment

I took a quick look at the Pathology Cytogenetic Studies - document. For the hematologic malignancies, they are all coded for those diseases "without mention of having achieved remission". However, as a Standard of Care, we repeat cytogenetics at the time of suspected remission in order to document a molecular remission for many hematologic neoplastic disorders (CML, myeloma, lymphoma, etc). However, with the current accepted ICD-9 codes, they would be excluded if we coded them as "in remission".

Response

We have included in remission codes where we have found them.

Indications and Limitations of Coverage and/or Medical Necessity

6. Comment

Constitutional chromosome abnormalities

Most laboratory cytogenetic analyses include standard G-banded chromosome analyses and/or molecular cytogenetic studies utilizing the method of fluorescence-in-situ- hybridization (FISH).

Response

We have included this language in the policy.

7. Comment

Constitutional chromosome abnormality studies may be undertaken *prenatally* to rule out the presence of an abnormality in the fetus. Reasons for referral may include:

- Advanced maternal age, abnormalities observed on ultrasound, and family history of a chromosome abnormality that increases risk for the current pregnancy.

- Studies are also performed on products of conception to determine whether a chromosome abnormality was responsible for a fetal loss.

Response

We have included this language in the policy

8. Comment

Studies may be undertaken *postnatally* to:

- Rule out chromosome abnormalities that may be associated with congenital anomalies, developmental delays, and/or mental retardation, and/or problems in sexual maturation or reproduction.
 - Abnormalities involved in these disorders may be of number or structure.
 - Specific FISH probes that can evaluate the abnormalities (microduplications or microdeletions) associated with neurologic and developmental issues, are now a part of routine cytogenetic practice.
- Rule out the presence of a balanced chromosomal rearrangement that put an individual at risk for having a child with multiple congenital anomalies or for risk of recurrent miscarriage.
- Rule out the presence of a chromosome instability syndrome that predisposes to development of malignancy.

Response

We have included this language in the policy

9. Comment

Acquired chromosome abnormalities

- Identifying the specific chromosome abnormality associated with hematologic malignancies is now required for differential diagnosis of all acute leukemias, many of the chronic lymphoid and myeloid leukemias as well as myelodysplastic syndromes.
 - Identification of these abnormalities has become important for determining therapeutic regimens.
- Chromosome abnormalities for diagnosis and therapy decisions have been identified in solid tumors including lymphomas, the small round blue cell tumors of childhood, and adult solid tumors such as breast, prostate, urinary bladder, lung and brain.

Response

We have included this language in the policy

10. Comment

II. CPT/HCPCS Codes

It is critical that the FISH codes remain in the policy and as many ICD-9 codes as possible are included for FISH. Currently, FISH assays are expanding into every organ system involved in oncology. Essentially, every ICD-9 code that may be involved with cancer should be listed.

88240	Cryopreservation, freezing and storage of cells, each cell line
88241	Thawing and expansion of frozen cells, each aliquot
88271	Molecular cytogenetics; DNA probe, each (e.g., fish)
88272	Molecular cytogenetics; chromosomal in situ Hybridization, analyze 3-5 cells (e.g., for derivatives and markers)
88273	Molecular cytogenetics; chromosomal in situ hybridization, analyze 10-30 cells (e.g., for microdeletions)
88274	Molecular cytogenetics; interphase in situ hybridization, analyze 25-99 cells

88275	Molecular cytogenetics; interphase in situ hybridization, analyze 100-300 cells
88291	Cytogenetics and molecular cytogenetics, interpretation and report
88299	Unlisted cytogenetic study

Response

All the listed codes remain in the policy.

III. ICD-9 Codes that Support Medical Necessity

Comment

Attachment A includes a comprehensive list of ICD-9 codes relating to cytogenetics. It is very important that all ICD-9 codes that support medical necessity are included. This list includes all of the ICD-9 codes from Trailblazer’s policy including the most recent 2010 ICD-9 codes.

Response

We have reviewed the comprehensive list of covered codes and have used many of them. In checking the literature it appears covering all cancers is premature at this time. We are aware that this is a rapidly expanding field and we will be glad to expand coverage as more literature becomes available; specifically literature that shows that the test will impact the treatment plan. Medicare does not cover screening tests so we have intentionally excluded codes that have that description. ICD-9 codes cannot be added solely based on the fact that they were listed in another contractor's LCD. There must be literature supporting its inclusion in the LCD.

11. Comment

Please note the following:

Invalid codes (effective October 1, 2009):

- 239.8 Neoplasm of unspecified nature of other specified sites
- 779.3 Feeding problems in newborn

Note the following 2 revised cytogenetic codes included in Attachment A:

- 757.6 Specified congenital anomalies of breast
- 793.99 Other nonspecific (abnormal) findings on radiological and other examinations of body structure

Response

We have noted the above.

12. Comment

IV. Documentation Requirements

Documentation requirements:

- Each claim must be submitted with ICD-9 codes that reflect the condition of the patient, and indicate the reason(s) for which the service was performed. Claims submitted without ICD-9 codes will be returned.
- A copy of the test results should be maintained in the patient medical records.

- The provider must maintain hard copy documentation of the test results and interpretation, along with copies of the ordering/referring physician's order for the studies.
- The physician must state the clinical indication/medical necessity for the study in the order for the test.

Response

Formatting was changed to make this section more clear.

13. Comment

V. Utilization Guidelines

Utilization requirements:

- Payments for cytogenetic studies for genetic disorders and failure of sexual development chromosomal abnormalities will be allowed once per lifetime.
 - This is in contrast to the malignancies, where repeat cytogenetic studies may be appropriate.
- If a new technique (e.g., fluorescence in-situ hybridization) becomes available that was not available at the time of initial diagnosis, or if a supplemental study is able to be performed at a higher level of resolution and this increases the chances of detection a chromosome abnormality, the follow-up study will be considered.

Response

Formatting was changed to make this section more clear.