

November 2023



SONIC HEALTHCARE
USA

Client Communication

Medicare Local Coverage Determination Policy: CGS

Coverage Policy

L37608- MDS FISH

CPT: 88271, 88273, 88274, 88275, 88291

Revision Effective Date: 06/30/2022

Coverage Indications, Limitations, and/or Medical Necessity

This policy provides coverage for indicated fluorescent in situ hybridization (FISH) probes for patients whose bone marrow examination is suggestive of myelodysplasia (MDS) and who have an inadequate cytogenetic assessment by conventional karyotyping. In general, conventional karyotype analysis is sufficient for confirmation for the diagnosis of MDS. MDS FISH studies should only be performed when there are fewer than 20 metaphases available for analysis, or an unresolved karyotype. Medicare will only cover up to 4 FISH studies (-7 or del(7q), -5 or del(5q), +8 and del(20q) on initial evaluation to diagnose MDS. Reflex testing for additional FISH markers to diagnose MDS is only reasonable and necessary when the initial 4 studies are negative or the diagnosis remains uncertain following the initial 4 probes.

Generally, FISH testing is not reasonable and necessary for MDS and provides little if any additional information to conventional karyotyping.

Indications

FISH testing is indicated in the evaluation of patients whose bone marrow examination are suggestive of MDS and who have had a failed or inadequate cytogenetic assessment (conventional karyotype).

Limitations

- When the results of conventional cytogenetics are adequate, FISH testing is not reasonable and necessary and not a Medicare benefit;
- When conventional karyotyping is inadequate, Medicare will limit initial FISH testing to 4 probes (studies) as specified above in this policy;
- Reflex FISH testing may be indicated when the initial 4 probes are negative;

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Diagnosis codes must be applicable to the patient's symptoms or conditions and must be consistent with the patient's medical record. Sonic Healthcare does not recommend any diagnosis codes and will only submit diagnosis information provided to us by the ordering physician or his/her designated staff.

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- Molecular next-generation sequence (NGS) testing alone (for myeloid mutations) or in combination with FISH testing is not reasonable and necessary for the diagnosis of MDS, and is not a Medicare benefit;
- When a patient has a bone marrow suggestive of another disorder (e.g., a plasma cell disorder), MDS-FISH is not indicated;
- Delay in diagnosis is not a legitimate reason for performing more than 4 initial FISH studies followed by step-wise reflex testing;
- Repeat FISH testing by another laboratory on the same specimen is not reasonable and necessary.

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The ICD10 codes listed below are the top 40 diagnosis codes Sonic most commonly receives from ordering physicians for this limited-coverage test. Medicare supports provider utilization of all the diagnosis codes listed below, except those notated in bold. If you are providing a diagnosis code that is bolded below, please submit a valid ABN form with the order. To view the complete policy and the full list of medically supported diagnosis codes, please refer to the CMS website for guidance:

<https://www.cms.gov/medicare-coverage-database/search.aspx>

Code	Description
D46.9	Myelodysplastic syndrome, unspecified
D51.0	Vitamin B deficiency anaemia due to intrinsic factor deficiency
M19.032	Primary osteoarthritis, left wrist

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