The Impact of Discrepant Payor Policies from One Lab Benefits Manager on Patient Access to Genetic Testing

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Introduction:

Insurance policies and medical necessity criteria are essential components of medical practice. Testing criteria can help direct testing of appropriate patients, if the criteria are consistent with accepted practice standards. The determination of medical necessity for hereditary cancer genetic testing is complex and has inherent difficulties that do not easily lend themselves to automation and/or scalability. To address this, health plans are increasingly contracting lab benefits managers (LBMs) to perform these services, aiming to control unnecessary testing and lower costs. This increased reliance on LBMs has raised concerns about the transparency of the processes and the resultant impact on patient access to care. While National Comprehensive Cancer Network (NCCN) testing criteria are widely accepted by both clinicians and health plans as the standard for hereditary cancer testing, some medical policies diverge significantly, with a resultant impact on patient access to testing. To date, the degree of this impact has not been investigated.

Methods:

We performed a retrospective study of participants referred for hereditary cancer panel testing at one commercial laboratory from 1/1/24 to 5/31/24 who met the NCCN testing criteria in the Genetic/Familial High-Risk Assessment: Breast, Ovarian and Pancreatic v3.2024 (“BOP”) guidelines and the Genetic/Familial High-Risk Assessment: Colon v2.2023 (“Colon”) guidelines. Clinical histories were obtained through review of clinical notes, pedigrees, test requisitions and other material provided by the ordering provider. Determination of whether participants met NCCN criteria was performed through manual review by trained clinical data curators. We identified all LBM criteria that were discrepant with NCCN; of note, none had evidence provided to support the discrepancy. We selected four BOP criteria and four Colon criteria that we expected would impact the most patients. We then mapped the histories of these NCCN-eligible patients to the corresponding LBM criterion to determine whether the patient also met the LBM criterion. Those participants meeting NCCN criteria but not meeting LBM criteria were designated as patients denied access to standard of care genetic testing.

Results:

Among the 2797 participants meeting NCCN BOP criteria, 1168 (42%) met for the four criteria we investigated, of which 34% (N=403) did not qualify for testing under the LBM’s corresponding four criteria. Among 578 participants meeting NCCN Colon criteria, 204 (35%) met for the four selected criteria of which 83% (N=169) did not qualify under the LBM’s policy. These patients impacted by limitations in the eight LBM criteria represent 5.7% of all patients meeting NCCN BOP testing criteria and 26% of all patients meeting NCCN Colon testing criteria in our cohort. Among those not covered by the LBM’s BOP criteria, 8.75% tested positive in one of 12 moderate or high penetrance breast cancer genes, and 7.24% of those not covered by the LBM’s Colon criteria tested positive in one of 19 moderate or high penetrance colon cancer genes.

Conclusions:

Application of testing criteria adopted by one large LBM resulted in a significant decrease in the number of patients eligible for hereditary cancer genetic testing. Given that we assessed only eight of the NCCN discrepancies among this LBM's policies, the full impact of their criteria changes is likely to be much greater. This discrepancy between the accepted NCCN guidelines and a prominent LBM guideline adds unnecessary complexity for busy clinicians when assessing patients for medical necessity. This study highlights that eligibility restrictions implemented by an LBM, without supporting evidence, significantly decreased access for individuals who would otherwise meet standard-of-care parameters for genetic testing for hereditary cancer. We also show that these patients had pathogenic variant prevalences of ~7-9% in clinically actionable genes, well within the risk range considered eligible for genetic testing.