**Measure Description**

Percentage of patients diagnosed with gastroesophageal adenocarcinoma (GEA) cancer (primary or metastatic) for which biopsies, resection, or metastatic specimens that have HER2 evaluation conducted using the current ASCO/CAP recommended manual system or computer-assisted system consistent with the optimal algorithm.

**INSTRUCTIONS:** This measure should be submitted when quantitative HER2 evaluation is conducted during the performance period for patients with gastroesophageal adenocarcinoma. This measure may be submitted by eligible clinicians who perform the quality actions described in the measure based on the services provided and the measure-specific denominator coding.

This measure has two performance rates that contribute to the overall performance score:

1. Percentage of all pathology reports for GEA cancer biopsies or resection specimens (primary or metastasis) for patients with known GEA that have HER2 immunohistochemistry (IHC) evaluation conducted using the current ASCO/CAP recommended optimal scoring algorithm completed.

2. Percentage of pathology reports GEA cancer patients with equivocal (IHC 2+) human epidermal growth factor receptor 2 (HER2) testing result that had a follow-up HER2 evaluation completed using in-situ hybridization (ISH).

The overall performance score submitted is a weighted average of: 

\[
\frac{Numerator 1 + Numerator 2}{Denominator 1 + Denominator 2}
\]

**Denominator Statement**

All pathology reports for GEA cancer patients with a tumor evaluation using HER2 IHC.

CPT®: 88342, 88360, 88361, 88365, 88367, 88368

AND

ICD-10:
- C15.3: Malignant neoplasm of upper third of esophagus
- C15.4: Malignant neoplasm of middle third of esophagus
- C15.5: Malignant neoplasm of lower third of esophagus
- C15.8: Malignant neoplasm of overlapping sites of esophagus
- C15.9: Malignant neoplasm of esophagus, unspecified
- C16.0: Malignant neoplasm of cardia
- C16.1: Malignant neoplasm of fundus of stomach
- C16.2: Malignant neoplasm of body of stomach
- C16.3: Malignant neoplasm of pyloric antrum
**DENOMINATOR EXCLUSIONS**

1. Numerator 1: GE cancers that are not of the adenocarcinoma histology subtype.
2. Numerator 2: GEAs with negative (IHC 0, IHC 1+) or positive (IHC 3+) HER2 IHC scores.

**DENOMINATOR EXCEPTIONS**

1. None

**NUMERATOR STATEMENT**

Numerator 1: GEA cancer biopsies or resection specimens (primary or metastatic) with an optimal scoring algorithm for HER2 IHC testing completed consistent with the current ASCO/CAP guideline.

HER2 IHC result may include:
- Negative (IHC 0)
- Negative (IHC 1+)
- Equivocal (IHC 2+)
- Positive (IHC 3+)
- Indeterminate

Numerator note: HER2 testing on fine-needle aspiration (FNA) specimens (cell blocks) is an acceptable alternative.

Numerator 2: GEA cancer patients with a result of IHC 2+ (equivocal) who had a follow up HER2 test using ISH.

HER2 ISH result may include:
- Negative (not amplified)
- Positive (amplified)
- Indeterminate

**NUMERATOR EXCLUSIONS**

None

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**MEASURE INFORMATION**

<table>
<thead>
<tr>
<th>NQS Domain</th>
<th>Communication and Care Coordination</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meaningful Measures Area(s)</td>
<td>Transfer of Health Information and Interoperability</td>
</tr>
<tr>
<td>Meaningful Measure Rationale</td>
<td>Gastroesophageal adenocarcinoma (GEA) is estimated to represent up to 43,280 cancer cases in the United States in 2016 (2) and represents the eighth (esophageal) and fifth (stomach) most common cancers worldwide (3).</td>
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</tbody>
</table>
Gastroesophageal adenocarcinoma is often diagnosed at an advanced stage, resulting in a poor prognosis. Most localized GEAs (stages II and III) are best treated with multimodality therapy, which can result in a five-year survival in ~40% of patients; however, once GEA is advanced (defined as unresectable local-regional, recurrent, or metastatic disease), therapies are limited and palliative with cure being extremely rare.

NCCN Guidelines recommend that specimens with 2+ expression of HER2 by IHC should be additionally assessed by FISH or other ISH method. Specimens with 3+ overexpression by IHC or FISH positivity (HER2: CEP17 ratio 2) are considered positive. Specimens having an IHC score of 0 or 1+ are considered negative and do not warrant further testing. Since the benefit from the addition of HER2-directed therapy correlates with HER2 protein expression, initial HER2 testing should be performed by IHC. In situ hybridization should be reserved for IHC 2+ cases (2).

All patients who have documented advanced GEA and who are considered good candidates for combination chemotherapy plus trastuzumab therapy should have their tumor tissue tested for HER2 overexpression and/or amplification. In patients with HER2-positive GEA, the addition of trastuzumab can increase the response rate, prolong progression-free survival, and prolong overall survival.


Measure Type: Process

Data Source: Laboratory Information Systems; pathology reports

Summary of Performance Gap Evidence: In 2012, ASCO and CAP convened an Update Committee to conduct a comprehensive review of the peer-reviewed literature published since 2006 and to revise the guideline recommendations. The Update Committee developed new algorithms for testing and recommended quality assurance monitoring that would make HER2 testing less variable and ensure more analytic consistency among laboratories. Because there are important distinct differences in HER2 expression, scoring, and outcomes in GEA relative to breast carcinoma, the need for HER2 guidelines (that include critical clinical and laboratory considerations) was recognized.

<table>
<thead>
<tr>
<th>Measure Owner</th>
<th>College of American Pathologists</th>
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<tbody>
<tr>
<td>NQF ID</td>
<td>N/A</td>
</tr>
<tr>
<td>Number of Performance Rates</td>
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</tr>
<tr>
<td>Overall Performance Rate</td>
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<tr>
<td>High-priority</td>
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<tr>
<td>Improvement Notation</td>
<td>Inverse Measure: No</td>
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<td></td>
<td>Proportional Measure: Yes (Higher score indicates better quality)</td>
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<td>Continuous Variable Measure: No</td>
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<td>Ratio Measure: No</td>
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<td>Risk-adjusted: No</td>
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<tr>
<td>Specialty</td>
<td>Pathology</td>
</tr>
</tbody>
</table>
| **Current Clinical Guideline the Measure is Derived From** | The following evidence statements are quoted verbatim from the referenced clinical guidelines and other reference:

When GEA HER2 status is being evaluated, laboratories/pathologists should perform/order IHC testing first followed by ISH when IHC result is 2+ (equivocal). Positive (3+) or negative (0 or 1+) HER2 IHC results do not require further ISH testing. (Strong recommendation) (1).

Specimens with 2+ expression of HER2 by IHC should be additionally assessed by FISH or other ISH method. Specimens with 3+ overexpression by IHC or FISH positivity (HER2: CEP17 ratio 2) are considered positive. Specimens having an IHC score of 0 or 1+ are considered negative and do not warrant further testing. (Strong recommendation) (2).


Measure Flow

Performance Rate 1

Start

Procedure as listed in the denominator (CPT: 88342, 88360, 88361, 88365, 88367, 88368)

No

No

Not included in eligible population for denominator

No

Procedure as listed in denominator (1/1/2019 - 12/31/2019)

Yes

Yes

Diagnosis of GE cancers that are not of the adenocarcinoma type

No

Denominator Exclusion = 100

No = 900

Eligible Population Included in the Denominator

Yes = 1000

Quantitative HER2 by IHC evaluation consistent with scoring system defined in the ASCO/CAP guidelines

No

Performance met; Data Completeness met

Yes = 700

Quantitative HER2 by IHC performed, scoring system defined in the ASCO/CAP guidelines not used, reason not otherwise specified

No = 100

Performance not met; Data Completeness met

Yes = 100

Data Completeness not met

No = 100

Data Completeness =

\[
\frac{\text{Performance Met} + \text{Performance Not Met}}{\text{Eligible Population}} = \frac{700 + 100}{900} = 88\%
\]

Performance Rate =

\[
\frac{\text{Performance Met}}{\text{Data Completeness Numerator}} = \frac{700}{900} = 78\%
\]

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CAP QCDR Measure
HER2 Evaluation and Repeat - Gastroesophageal Adenocarcinoma (GEA)

Performance Rate 2

Start

Procedure as listed in the denominator (CPT: 88342, 88360, 88361, 88363, 88365, 88367, 88368)

Yes = 1000

No = 0

Not included in eligible population for denominator

Procedure as listed in denominator (1/1/2019 – 12/31/2019)

Yes = 1000

No = 0

Denominator Exclusion = 500

GEAs with negative (IHC 0; IHC 1+) or positive (IHC 3+) HER2 IHC scores

Yes = 500

Data Completeness not met

Data Completeness = Performance Met + Performance Not Met
Eligible Population = 500

Performance Rate = Performance Met
Data completeness Numerator = 500

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Weighted Score: (Numerator 1 + Numerator 2)/(Denominator 1 + Denominator 2)
Overall Performance Score = (700+300)/(900+500)
= 72% (Score submitted to CMS)