CMS Measure ID/CMS QCDR ID: CAP 12

Measure Title: Accurate Human Epidermal Growth Factor Receptor 2 (HER2) Tumor Evaluation and Repeat Evaluation in Patients with Gastroesophageal Adenocarcinoma (GEA)

Measure Specifications

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: (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

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	• C16.4: Malignant neoplasm of pylorus • C16.5: Malignant neoplasm of lesser curvature of stomach, unspecified • C16.6: Malignant neoplasm of greater curvature of stomach, unspecified • C16.8: Malignant neoplasm of overlapping sites of stomach • C16.9: Malignant neoplasm of stomach, unspecified
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
Measure Information	
NQS Domain	Communication and Care Coordination
Meaningful Measures Area(s)	Transfer of Health Information and Interoperability
Meaningful Measure Rationale	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).

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	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. 1. Ajani JA, D'Amico TA, Almhanna K, et al. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines). Gastric Cancer, version 3.2015. National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed June 28, 2016. 2. Cancer facts & figures: worldwide data. World Cancer Research Fund International Web site. http://www.wcrf.org/int/cancer-facts-figures/worldwidedata. Accessed June 28, 2016.
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. 1. Bartley AN, Washington K, Ventura CB, et al. HER2 testing and clinical decision making in gastroesophageal adenocarcinoma: guideline from the College of American Pathologists, American Society for Clinical Pathology and the American Society of Clinical Oncology. Arch Pathol Lab Med. 2016;140(12):1345-1363. doi: 10.5858/arpa.2016-0331-CP.

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Measure Owner	College of American Pathologists
NQF ID	N/A
Number of Performance Rates	1
Overall Performance Rate	1st Performance Rate
High-priority	Yes
Improvement Notation	Inverse Measure: No **Proportional Measure: Yes (Higher score indicates better quality)** Continuous Variable Measure: No Ratio Measure: No Risk-adjusted: No
Specialty	Pathology
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.[5] Specimens having an IHC score of 0 or 1+ are considered negative and do not warrant further testing. (Strong recommendation) (2). 1. Bartley AN, Washington K, Ventura CB, et al. HER2 testing and clinical decision making in gastroesophageal adenocarcinoma: guideline from the College of American Pathologists, American Society for Clinical Pathology and the American Society of Clinical Oncology. Arch Pathol Lab Med. 2016;140(12):1345-1363. doi: 10.5858/arpa.2016-0331-CP 2. Ajani JA, D'Amico TA, Almhanna K, et al. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines). Gastric Cancer, version 3.2015. National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed June 28, 2016.

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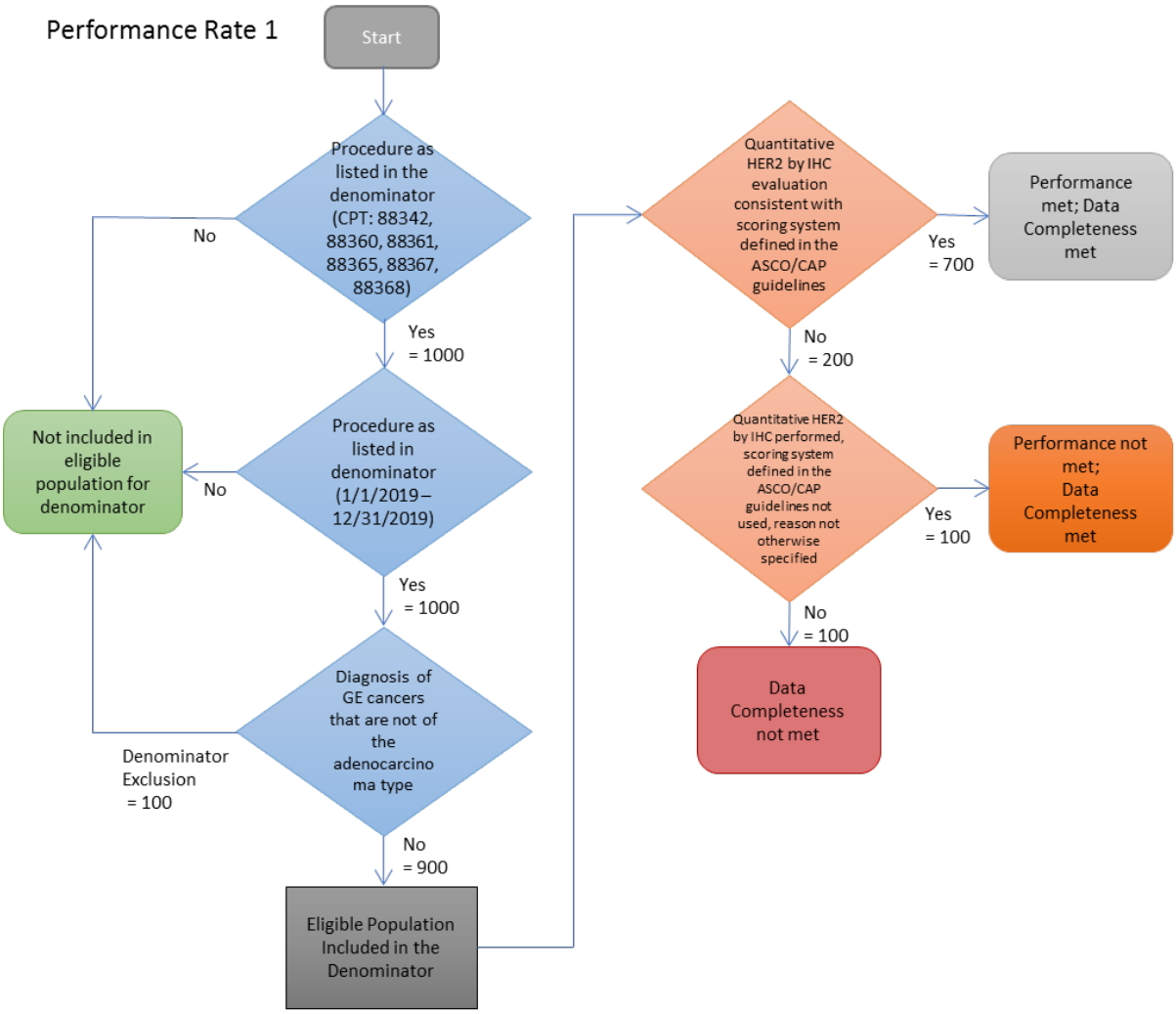
Measure Flow



Data Completeness =
Performance Met + Performance Not Met 700 + 100
---------- = ---------- = 88%
Eligible Population 900

Performance Rate =
Performance Met 700
---------- = ------- = 78%
Data Completeness Numerator 900

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*See the posted measure specifications for the specific coding and instructions to submit this measure.

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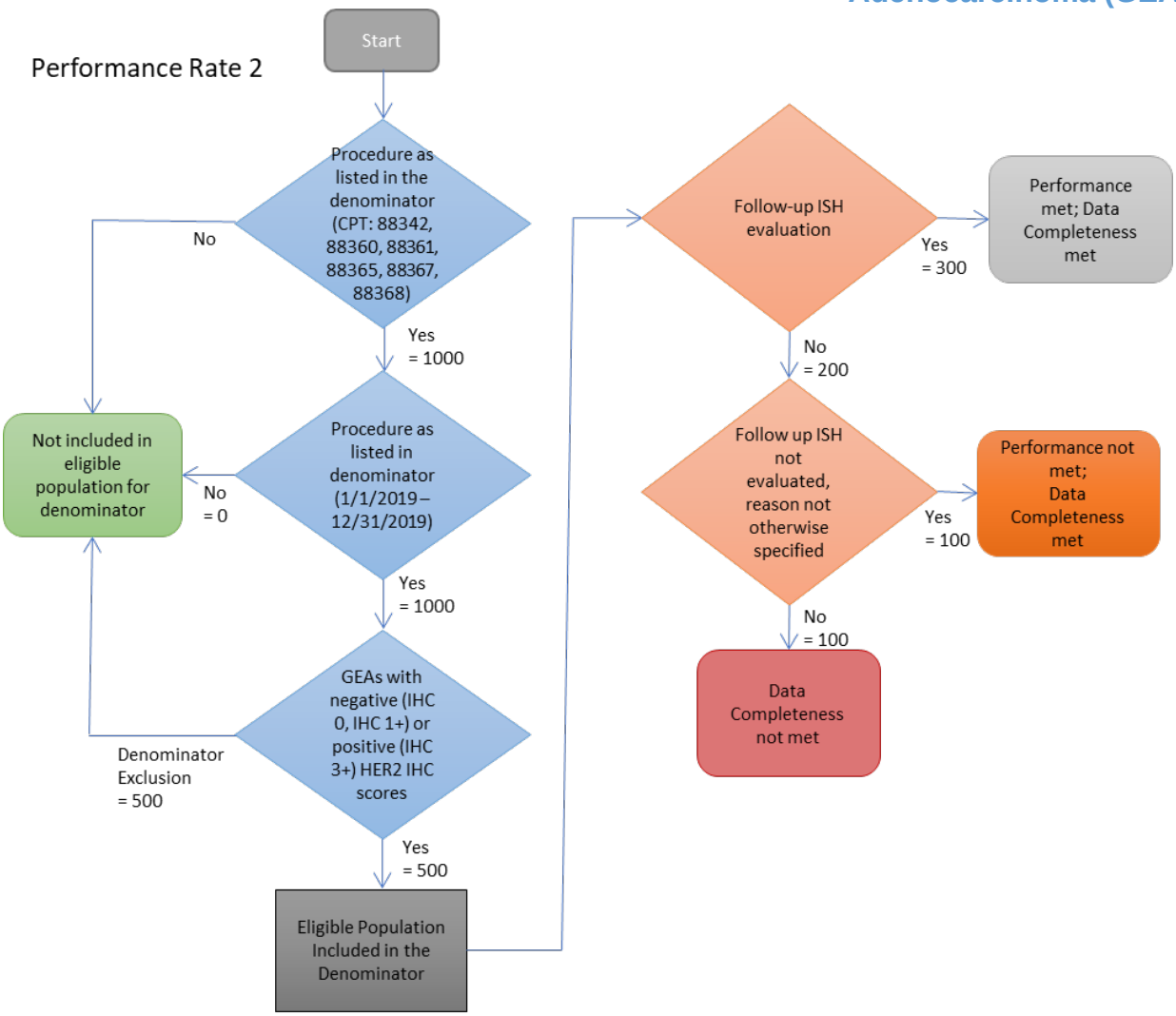
Performance Rate 2



Data Completeness = Performance Met + Performance Not Met / Eligible Population	300 + 100 / 500 = 80%
Performance Rate = Performance Met / Data completeness Numerator	300 / 500 = 60%

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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)

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