



**CMS Measure ID/CMS QCDR ID: CAP 20**

**Measure Title: High Risk HPV Testing and p16 Scoring in Surgical Specimens for Patients with Oropharyngeal Squamous Cell Carcinoma (OPSCC)**

Measure Specifications

<p><b>Measure Description</b></p>	<p>Percentage of surgical pathology reports for invasive oropharyngeal squamous cell carcinoma (OPSCC) with HR-HPV testing by surrogate marker p16 performed AND that include quantitative p16 immunohistochemistry (IHC) results.</p> <p>INSTRUCTIONS: This measure has two performance rates that contribute to the overall performance score:</p> <ol style="list-style-type: none"> <li>1. Percentage of surgical pathology reports for invasive OPSCC with HR-HPV testing by surrogate marker p16 IHC performed.</li> <li>2. Percentage of surgical pathology reports for invasive OPSCC with HR-HPV testing by surrogate marker p16 IHC performed AND that include quantitative p16 IHC results based on the ≥70% nuclear and cytoplasmic staining.</li> </ol> <p>The overall performance score submitted is a simple average of: (Performance rate 1 + Performance rate 2)/2.</p>
<p><b>Denominator Statement</b></p>	<p>All surgical pathology reports with a diagnosis of invasive OPSCC. CPT®: 88305, 88309</p> <p><b>AND</b> ICD10:</p> <ul style="list-style-type: none"> <li>• C01: Malignant neoplasm of base of tongue</li> <li>• C05.1: Malignant neoplasm of soft palate</li> <li>• C09.0: Malignant neoplasm of tonsillar fossa</li> <li>• C09.1: Malignant neoplasm of tonsillar pillar (anterior) (posterior)</li> <li>• C09.8: Malignant neoplasm of overlapping sites of tonsil</li> <li>• C09.9: Malignant neoplasm of tonsil, unspecified</li> <li>• C10.0: Malignant neoplasm of vallecula</li> <li>• C10.1: Malignant neoplasm of anterior surface of epiglottis</li> <li>• C10.2: Malignant neoplasm of lateral wall of oropharynx</li> <li>• C10.3: Malignant neoplasm of posterior wall of oropharynx</li> <li>• C10.4: Malignant neoplasm of branchial cleft</li> <li>• C10.8: Malignant neoplasm of overlapping sites of oropharynx</li> <li>• C10.9: Malignant neoplasm of oropharynx, unspecified</li> <li>• C14.0: Malignant neoplasm of pharynx, unspecified</li> <li>• C14.2: Malignant neoplasm of Waldeyer's ring</li> <li>• C14.8: Malignant neoplasm of overlapping sites of lip, oral cavity and pharynx</li> </ul> <p>Denominator definition: Includes invasive OPSCC reports for specimens from primary tumors (tonsils, soft palate, or base of tongue (posterior to circumvallate papillae) and lateral and posterior pharyngeal walls) or other site with metastatic OPSCC.</p>



<b>Denominator Exclusions</b>	None
<b>Denominator Exceptions</b>	Documentation of reason(s) p16 IHC testing was not performed (e.g., payor-related limitations, patients who have declined testing, patients receiving hospice)
<b>Numerator Statement</b>	<p>Numerator 1: Pathology reports with HR-HPV testing by surrogate marker p16 IHC performed</p> <p>Numerator 2: Pathology reports with HR-HPV testing by surrogate marker p16 IHC performed AND the quantitative p16 IHC result was derived using the <math>\geq 70</math> nuclear and cytoplasmic staining*</p> <p>Numerator 2 guidance Quantitative p16 IHC results may include:</p> <ul style="list-style-type: none"> <li>• p16 IHC positive (<math>\geq 70\%</math> nuclear and cytoplasmic moderate to strong staining)</li> <li>• p16 IHC negative (<math>&lt; 70\%</math> nuclear and cytoplasmic moderate to strong staining)</li> <li>• p16 previously performed</li> <li>• p16 cannot be determined</li> </ul> <p>*p16 quantitation: Results must be based on <math>\geq 70\%</math> nuclear and cytoplasmic staining with at least moderate to strong intensity.</p>
<b>Numerator Exclusions</b>	None
<b>Measure Information</b>	
<b>NQS Domain</b>	Communication and Care Coordination
<b>Meaningful Measures Area(s)</b>	Transfer of Health Information and Interoperability
<b>Meaningful Measure Rationale</b>	<p>Human papillomavirus (HPV) is a major cause of oropharyngeal squamous cell carcinoma (OPSCC) and has contributed to its increased incidence (1). HPV-positive OPSCC differs from HPV-negative OPSCC related to other risk factors including alcohol and tobacco use and has an improved response to treatment and better prognosis (2).</p> <p>Therefore, it is crucial to determine the HPV status of squamous cell carcinomas of the oropharynx, as treating clinicians utilize this information when developing a treatment plan for patients, which may include less aggressive treatment modalities. In the clinical setting, p16 IHC is an approach used to reliably diagnose HPV-induced OPSCC.</p> <p>The p16 test is considered to best stratify patient survival outcomes while also being practical and inexpensive (3). Furthermore, data suggest that the</p>



	<p>correlation between HPV positivity and p16 overexpression is highest when the <math>\geq 70\%</math> staining for p16 overexpression is applied (4).</p> <ol style="list-style-type: none"> <li>1. Chaturvedi AK, Engels EA, Pfeiffer RM, et al. Human papillomavirus and rising oropharyngeal cancer incidence in the United States. <i>J Clin Oncol.</i> 2011;29(32):4294–4301.</li> <li>2. Wang MB, Liu IY, Gornbein JA, Nguyen CT. HPV-positive oropharyngeal carcinoma: a systematic review of treatment and prognosis. <i>Otolaryngol Head Neck Surg.</i> 2015. Nov;153(5):758-69.</li> <li>3. Lewis JS Jr, Beadle B, Bishop JA, Chemock RD, Colasacco C, Lacchetti C, et al. Human papillomavirus testing in head and neck carcinomas: guideline from the College of American Pathologists. <i>Arch Pathol Lab Med.</i> 2018;142:559–597.</li> <li>4. Grønhøj Larsen C, Gyldenløve M, Jensen DH, Therkildsen MH, Kiss K, Norrild B, Konge L, von Buchwald C. Correlation between human papillomavirus and p16 overexpression in oropharyngeal tumours: a systematic review. <i>Br J Cancer.</i> 2014. Mar 18;110(6):1587-94.</li> </ol>
<b>Measure Type</b>	Process
<b>Data Source</b>	Laboratory Information Systems; pathology reports
<b>Summary of Performance Gap Evidence</b>	<p>Human papillomavirus (HPV) is a major cause of oropharyngeal squamous cell carcinoma (OPSCC) and has contributed to its increased incidence (1). HPV-positive OPSCC differs from HPV-negative OPSCC related to other risk factors including alcohol and tobacco use and has an improved response to treatment and better prognosis (2). Therefore, it is crucial to determine the HPV status of squamous cell carcinomas of the oropharynx, as treating clinicians utilize this information when developing a treatment plan for patients, which may include less aggressive treatment modalities. In the clinical setting, p16 IHC is an approach used to reliably diagnose HPV-induced OPSCC. The p16 test is considered to best stratify patient survival outcomes while also being practical and inexpensive (3). Furthermore, data suggest that the correlation between HPV positivity and p16 overexpression is highest when the <math>\geq 70\%</math> staining for p16 overexpression is applied (4).</p> <ol style="list-style-type: none"> <li>1. Chaturvedi AK, Engels EA, Pfeiffer RM, et al. Human papillomavirus and rising oropharyngeal cancer incidence in the United States. <i>J Clin Oncol.</i> 2011;29(32):4294–4301.</li> <li>2. Wang MB, Liu IY, Gornbein JA, Nguyen CT. HPV-positive oropharyngeal carcinoma: a systematic review of treatment and prognosis. <i>Otolaryngol Head Neck Surg.</i> 2015. Nov;153(5):758-69.</li> <li>3. Lewis JS Jr, Beadle B, Bishop JA, Chemock RD, Colasacco C, Lacchetti C, et al. Human papillomavirus testing in head and neck carcinomas: guideline from the College of American Pathologists. <i>Arch Pathol Lab Med.</i> 2018;142:559–597.</li> <li>4. Grønhøj Larsen C, Gyldenløve M, Jensen DH, Therkildsen MH, Kiss K, Norrild B, Konge L, von Buchwald C. Correlation between human papillomavirus and p16 overexpression in oropharyngeal tumours: a systematic review. <i>Br J Cancer.</i> 2014. Mar 18;110(6):1587-94.</li> </ol>

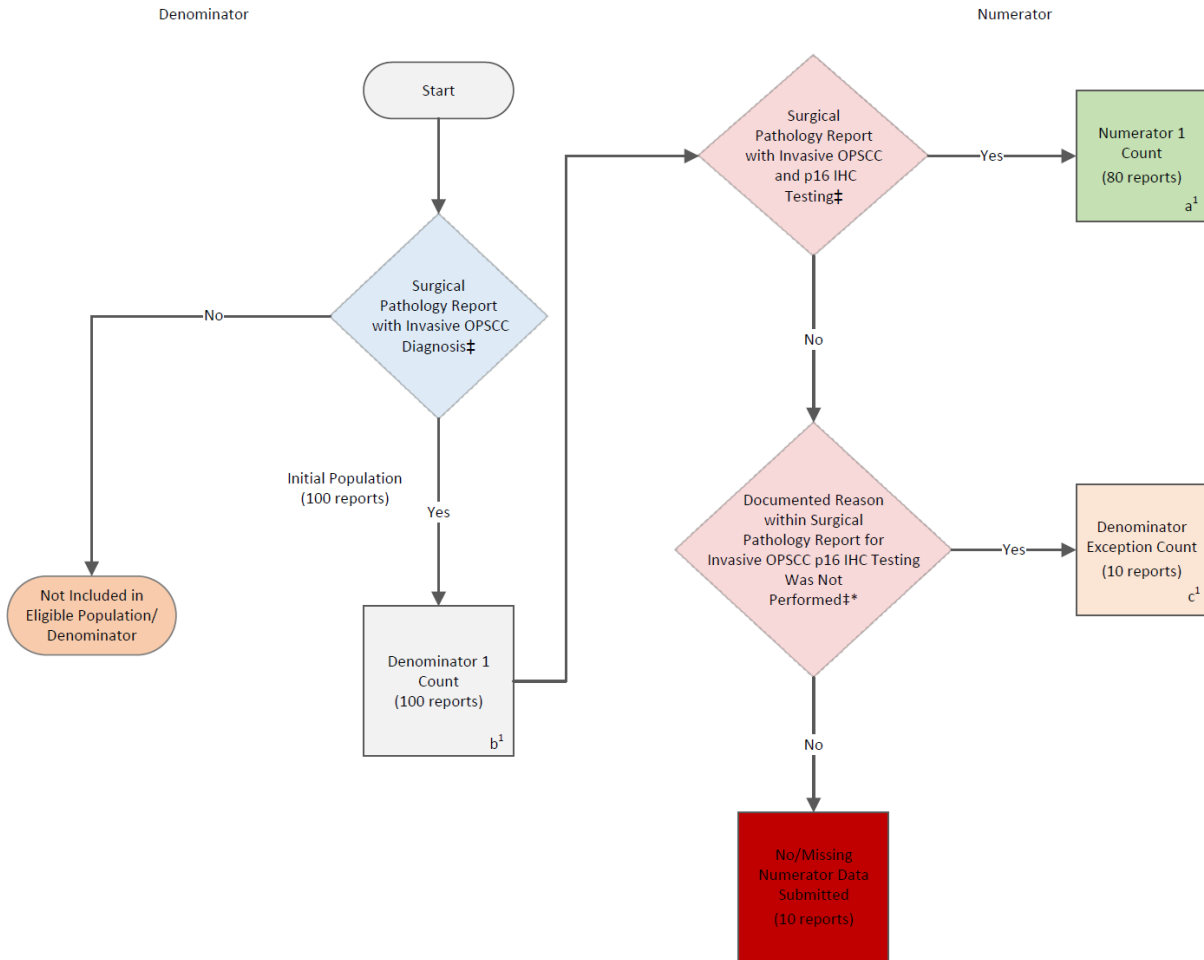


<b>Measure Owner</b>	College of American Pathologists
<b>NQF ID</b>	N/A
<b>Number of Performance Rates</b>	1
<b>Overall Performance Rate</b>	1 <sup>st</sup> Performance Rate
<b>High-priority</b>	Yes
<b>Improvement Notation</b>	Inverse Measure: No <b>Proportional Measure: Yes (Higher score indicates better quality)</b> Continuous Variable Measure: No Ratio Measure: No Risk-adjusted: No
<b>Specialty</b>	Pathology
<b>Current Clinical Guideline the Measure is Derived From</b>	<p>Pathologists should perform high-risk human papillomavirus (HR-HPV) testing on all patients with newly diagnosed oropharyngeal squamous cell carcinoma (OPSCC), including all histologic subtypes. This testing may be performed on the primary tumor or on a regional lymph node metastasis when the clinical findings are consistent with an oropharyngeal primary (Strong Recommendation) (1).</p> <p>For oropharyngeal tissue specimens (i.e., noncytology), pathologists should perform HR HPV testing by surrogate marker p16 immunohistochemistry (IHC). Additional HPV-specific testing may be done at the discretion of the pathologist and/or treating clinician, or in the context of a clinical trial (Recommendation) (1).</p> <p>Pathologists should report p16 IHC positivity as a surrogate for HR-HPV in tissue specimens (i.e., noncytology) when there is at least 70% nuclear and cytoplasmic expression with at least moderate to strong intensity (Expert Consensus Opinion) (1).</p> <p>Tumor human papillomavirus (HPV) testing by p16 immunohistochemistry (IHC) required as part of the workup for cancer of the oropharynx (Category 2A) (2).</p> <ol style="list-style-type: none"> <li>1. Lewis JS Jr, Beadle B, Bishop JA, Chemock RD, Colasacco C, Lacchetti C, et al. Human papillomavirus testing in head and neck carcinomas: guideline from the College of American Pathologists. Arch Pathol Lab Med. 2018;142:559–597.</li> <li>2. Pfister DG, Spencer S, Adelstein D, Adkins D, Brizel DM, Burtness B, et al. NCCN clinical practice guidelines in oncology: head and neck cancers, version 2.2018. National Comprehensive Cancer Network. Available at <a href="https://www.nccn.org/professionals/physician_gls/recently_updated.aspx">https://www.nccn.org/professionals/physician_gls/recently_updated.aspx</a></li> </ol>



Measure Flow

Population Criteria 1 – Performance Rate 1



‡Please refer to the specific section of the measure specification to identify the associated value sets or direct reference codes for use in submitting this measure, or to identify the Definition of the criteria associated with population criteria.

\*Documented reasons include payer-related limitations, patients who have declined testing, and patients receiving hospice.

**Performance Rate 1 =**

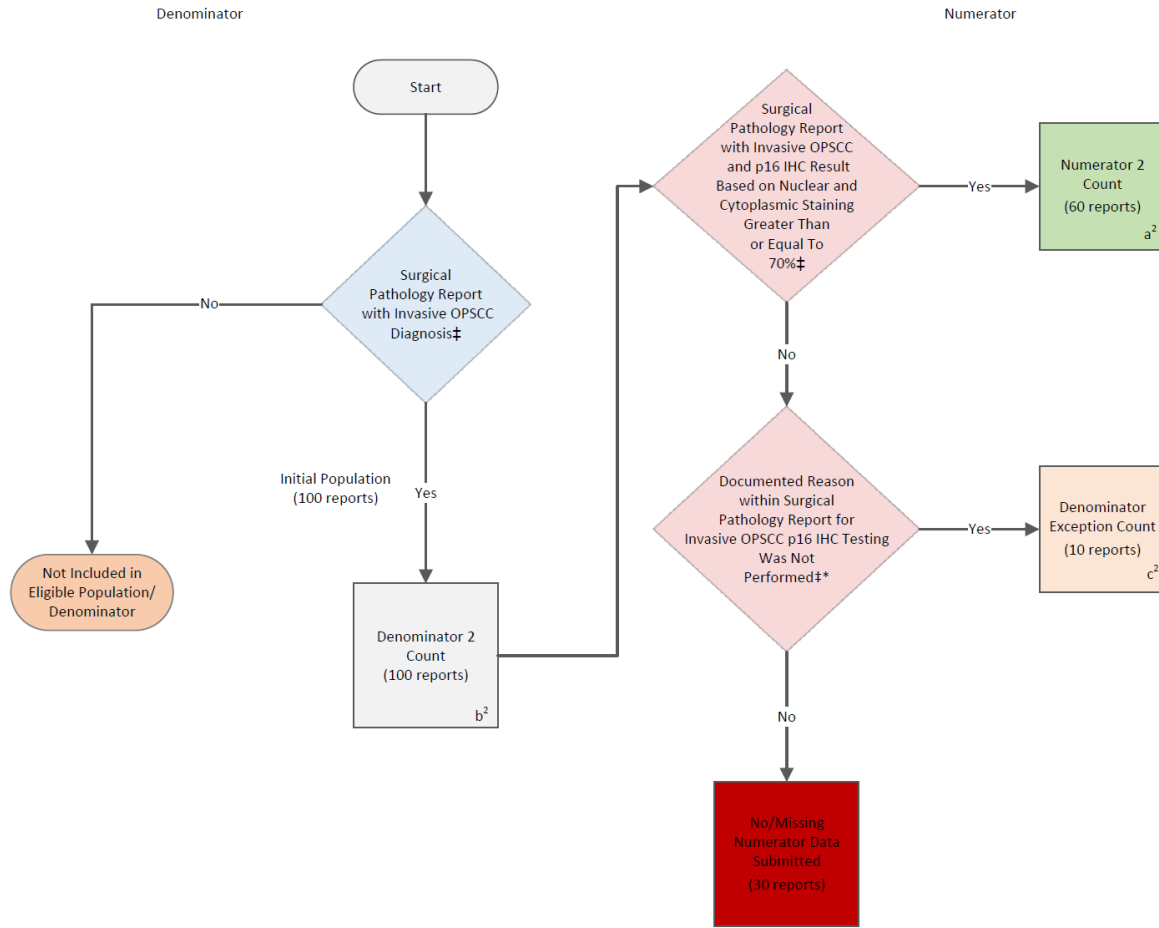
**SAMPLE CALCULATION:**

$$\frac{\text{Numerator (a}^1 = 80 \text{ reports)}}{\text{Denominator (b}^1 = 100 \text{ reports) - Denominator Exceptions (c}^1 = 10 \text{ reports)}} = 88.9\%$$

**DISCLAIMER:** Please refer to the measure specification for a complete listing of required data elements, value sets, direct reference codes, and logic definitions. The measure diagrams were developed as a supplement resource to be used in conjunction with the measure specifications. They should not be used alone or as a substitution for the measure specification.



Population Criteria 2 – Performance Rate 2



‡Please refer to the specific section of the measure specification to identify the associated value sets or direct reference codes for use in submitting this measure, or to identify the Definition of the criteria associated with population criteria.

\*Documented reasons include payor-related limitations, patients who have declined testing, and patients receiving hospice.

**Performance Rate 2 =**

**SAMPLE CALCULATION:**

$$\frac{\text{Numerator (a}^2 = 60 \text{ reports)}}{\text{Denominator (b}^2 = 100 \text{ reports) - Denominator Exceptions (c}^2 = 10 \text{ reports)}} = 66.7\%$$

**DISCLAIMER:** Please refer to the measure specification for a complete listing of required data elements, value sets, direct reference codes, and logic definitions. The measure diagrams were developed as a supplement resource to be used in conjunction with the measure specifications. They should not be used alone or as a substitution for the measure specification.