Overview of the tonsillectomy and adenoidectomy episode of care

State of Ohio

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1. CLINICAL OVERVIEW AND RATIONALE FOR DEVELOPING THE TONSILLECTOMY EPISODE

1.1 Rationale for developing the tonsillectomy episode of care

In the United States, Ear, Nose, and Throat (ENT) surgeons perform more than 530,000 tonsillectomies on children under the age of 15 annually.[1] This makes up 16% of all ambulatory surgeries for this age group. Between 1977 and 1989, the tonsillectomy incidence rate declined.[2] However, within the last 35 years, tonsillectomy rates have increased, partly due to a shift in the indications away from recurrent sore throats and towards sleep-disordered breathing.[3] For pediatric patients suffering from sleep-disordered breathing, related procedures such as adenoidectomy or concurrent adenoidectomy and tonsillectomy (adenotonsillectomy) are often performed with tonsillectomies.[4] The indications for tonsillectomy and adenoidectomy are well established. The most common indications for tonsillectomy are recurrent bacterial throat infections and sleep-disordered breathing. Studies show a tonsillectomy can reduce frequency and severity of throat infections.[5] Tonsillectomies can also improve or resolve sleep-disordered breathing.[6]

In the U.S., the current incidence rate for concurrent tonsillectomy and adenoidectomy is 1.46 per thousand children.[7] Ohio Medicaid beneficiaries age 20 or younger received over 7,500 such procedures in 2014. This represents approximately $17.1 million in spend at a median cost of $2,119 per episode.[8]

There are many opportunities to improve guideline-concordant care in order to support good patient outcomes. Evidence-based clinical guidelines recommended by the American Academy of Otolaryngology head and Neck Surgery (AAO HNS)

1 Archer, Sanford, Richard Rosenfeld, Ron Mitchell, and Reginald Baugh. "Clinical Practice Guideline: Tonsillectomy in Children." Otolaryngology - Head and Neck Surgery 143.2 (2010).

2 Derkay, Craig S. "Pediatric Otolaryngology Procedures in the United States: 1977–1987." International Journal of Pediatric Otorhinolaryngology 25.1-3 (1993): 1-12.

3 Mitchell, R.b. "Changes in Incidence and Indications of Tonsillectomy and Adenotonsillectomy, 1970-2005." Yearbook of Otolaryngology-Head and Neck Surgery 2010 (2010): 175-76.

4 Mitchell, Ron B. "Adenotonsillectomy for Obstructive Sleep Apnea in Children: Outcome Evaluated by Pre- and Postoperative Polysomnography." The Laryngoscope 117.10 (2007): 1844-854.

5 Paradise, J. L. "Efficacy Of Tonsillectomy For Recurrent Throat Infection In Severely Affected Children." The Pediatric Infectious Disease Journal 3.4 (1984): 374.

6 Mitchell, Ron B., and James Kelly. "Outcomes and Quality of Life following Adenotonsillectomy for Sleep-Disordered Breathing in Children." Orl 69.6 (2007): 345-48.

7 Bhattacharyya, Neil, and Harrison W. Lin. "Changes and Consistencies in the Epidemiology of Pediatric Adenotonsillar Surgery, 1996-2006." Otolaryngology - Head and Neck Surgery 143.5 (2010): 680-84.

8 Analysis of Ohio Medicaid claims data for dates between January 1, 2014 and December 31, 2014.

outline several best practices for clinicians to improve quality of care and outcomes for patients.[1] These guidelines recommended a single intra-operative dose of dexamethasone to help prevent postoperative nausea and vomiting, one of the most common complications of tonsillectomy. Guidelines also recommend against the prescription of perioperative antibiotics.[1]

Despite these clinical guidelines, surgical and treatment practices during the operative and perioperative periods of a tonsillectomy vary widely from one provider to another. Unique patient needs will necessitate variation in surgical and treatment practice; however, practice variation due to reasons not related to the patient may lead to sub-optimal patient outcomes, loss of resources, or both.

Implementing the tonsillectomy episode of care is intended to improve patient outcomes and reduce unnecessary practice variation by incentivizing evidence-based, guideline concordant care through an outcomes-centered payment model. Alongside other episodes of care and patient centered medical homes, the tonsillectomy episode will contribute to a model of care delivery that benefits patients through improved care quality and clinical outcomes, and a lower overall cost of care.

1.2 Clinical overview and typical patient journey for a tonsillectomy and / or adenoidectomy procedure

The scope of this episode includes tonsillectomies, tonsillectomies performed alongside an adenoidectomy (adenotonsillectomy), and adenoidectomies alone. A tonsillectomy, adenoidectomy, or combined adenotonsillectomy procedure will trigger a tonsillectomy episode. A tonsillectomy is a routine surgical procedure involving the complete removal of the tonsils by dissecting the peritonsillar space between the capsule and the wall of the throat. An adenoidectomy is a routine surgical procedure involving the complete removal of the adenoids. Adenoidectomies are included in the scope of the tonsillectomy episode for several reasons. First, the most common indications for adenoidectomy (e.g., nasal obstruction) overlap with those for tonsillectomy. Pediatric patients with sleep-disordered breathing might receive an adenoidectomy, a tonsillectomy, or both. Second, tonsillectomies and adenoidectomies are performed concurrently more often than either procedure alone in Ohio, and analyses have shown that adenoidectomies performed alone have a similar clinical pathway and spend profile as compared to concurrent tonsillectomies and adenotonsillectomies.

The patient journey begins when the patient experiences signs and symptoms that are clinical indications for a tonsillectomy or adenoidectomy, including sleep-disordered breathing. Sleep-disordered breathing can range from snoring to obstructive sleep apnea. Other possible indications include recurrent throat or ear infections as well as difficulty swallowing or breathing. A clinician will schedule the procedure after performing an initial assessment, including a detailed medical history. It is important that the effects of sleep-disordered breathing, recurrent otitis media, or recurrent sore

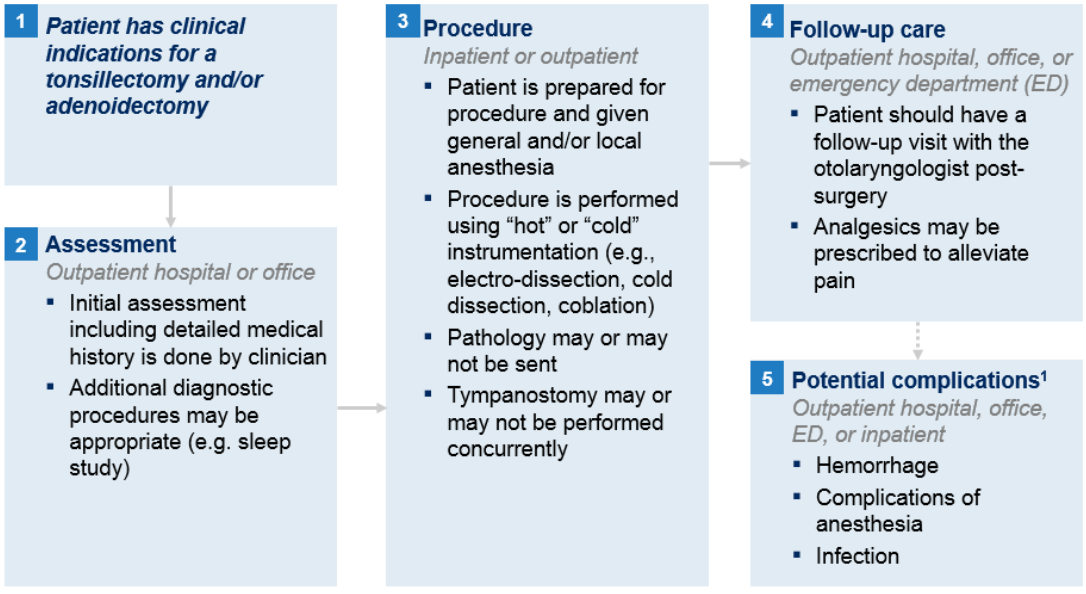
throats on the patient's quality of life be assessed in order to determine the possible benefits of surgery. The patient may receive other diagnostic testing, such as a chest x-ray or a sleep study to confirm the indicating diagnoses.

The procedure can be performed in an inpatient, outpatient, or ambulatory surgical center setting. The patient may be administered general anesthesia, and the surgery will be performed using either "hot" or "cold" methodology. The surgeon may choose to send a sample for pathology, and may perform a concurrent tympanostomy. After the procedure, the patient is typically discharged on the same day.

After the surgery, the patient should receive post-surgical follow-up care, including a follow-up visit with the surgeon. Pain management may be necessary, including the prescription of analgesics.

Patients may develop complications both during the procedure and afterwards. Potential complications include infection of the surgical site, persistent bleeding, and complications of anesthesia[1]. Some patients may be admitted after the procedure, though admission for recovery is generally not necessary. Most patients will receive follow-up visits to assess whether the surgery has improved their quality of life, indicated by the reduction of consistent sore throats or ear infections, or a reduction in the negative effects of sleep-disordered breathing.

EXHIBIT 1 – TONSILLECTOMY/ADENOIDECTOMY PATIENT JOURNEY



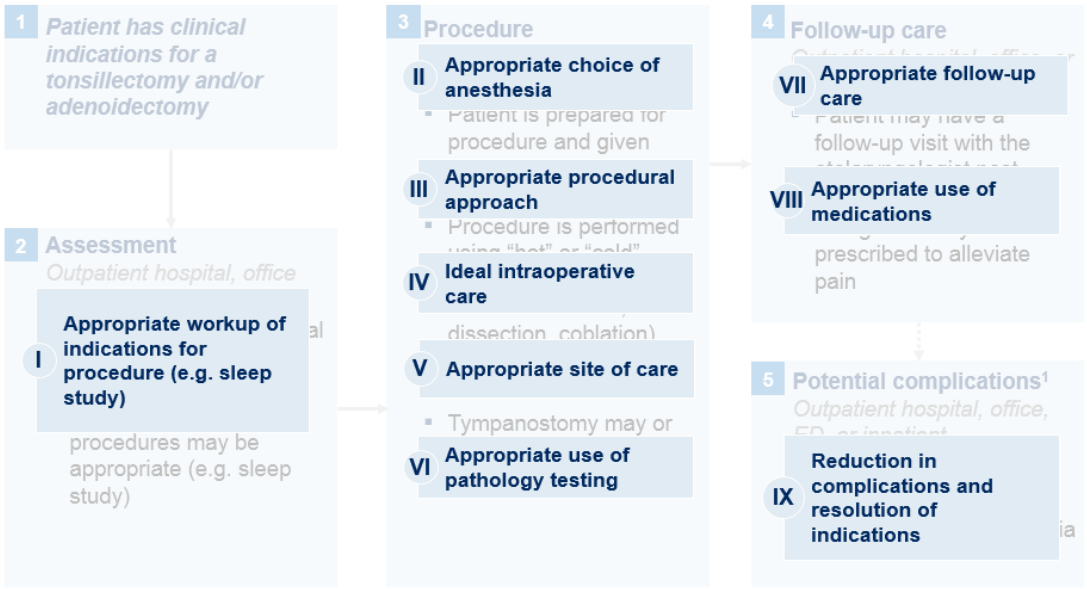
1 List of potential complications is not exhaustive
SOURCE: Clinical experts, UpToDate, AAP, AAO-HNS, AAFP, NIH, Medscape

Source: Clinical expert interviews; team analysis; main patient flows shown only

1.3 Potential sources of value within the patient journey

Within the tonsillectomy and adenoidectomy episode, providers have several opportunities to improve quality of care and reduce unnecessary spend associated with the episode (see Exhibit 2). Providers can follow best practice clinical guidelines to reduce unnecessary variation within the episode. For example, providers can make use of appropriate imaging and testing, including sleep studies and chest x-rays, to ensure the appropriateness of the procedure, including the appropriateness of any concurrent tympanostomy. Ideal intraoperative care, like the use of dexamethasone, can reduce the possibility of immediate complications. Providers can also perform only necessary pathology and ensure appropriate use of anesthesia during the procedure. By avoiding contraindicated practices such as perioperative antibiotics, providers can improve patient outcomes and reduce costs. Other sources of value include the choice of care setting, including performing the procedure in an ambulatory surgical center and avoiding admission whenever possible. Providers can also perform timely follow-ups after discharge from the hospital or surgical center. Taken together, these improvements may help to reduce long term complications and decrease costs while resolving the indications for the procedure.

EXHIBIT 2 – TONSILLECTOMY SOURCES OF VALUE



SOURCE: Clinical experts, UpToDate, AAP, AAO-HNS, AAFP, NIH, Medscape

2. OVERVIEW OF THE TONSILLECTOMY EPISODE DESIGN

2.1 Episode Trigger

A professional claim including a planned tonsillectomy, adenoidectomy, or adenotonsillectomy procedure performed in an inpatient or outpatient setting will trigger an episode (see Table 1 in Appendix for the lists of triggering CPT codes).

2.2 Principal Accountable Provider

The principal accountable provider (PAP) is the person or entity best positioned to influence the patient journey and clinical decisions throughout the episode. For the tonsillectomy episode, the PAP is the surgeon who performed the surgery. Because this provider is directly involved in the procedure, he or she is in the best position to promote adherence to guidelines, prevent complications, and influence other sources of value (see Exhibit 5 in the Appendix for the distribution of average non-risk adjusted spend by PAP).

2.3 Episode Duration

The tonsillectomy episode begins 30 days prior to the triggering procedure (called the "pre-trigger window"), includes the day of the procedure and any admission required for recovery from the procedure (called the "trigger window"), and ends 30 days afterwards (called the "post-trigger window"). The 30-day pre-trigger window was deemed an appropriate period of time to capture the majority of pre-operative diagnostics, workup, and management. The rationale for having one post-trigger window relates to included services and is described in greater detail in section 2.4.

2.4 Included Services

The episode model is designed to address spend for care and services directly related to the diagnosis, treatment, and immediate recovery phase for patients undergoing a tonsillectomy procedure. Each period of the patient journey, or episode "window," has a distinct claim inclusion logic derived from two major criteria: 1) that the type of included care and services must correspond to that period of the patient journey and 2) that the included care and services are understood to be directly or indirectly influenced by the PAP during that period.

The tonsillectomy episode is comprised of three distinct windows for the purpose of spend inclusions: a pre-trigger window, a trigger window, and a post-trigger window. During the pre-trigger window, all specific evaluation and management encounters (e.g., office or clinic visits with the PAP) and relevant pre-operative imaging and testing (e.g., sleep study, laryngoscopy) are included. During the trigger window—when the procedure and potential associated admission occurs—all medical spend

and certain pharmacy spend for relevant medications (e.g., analgesics, NSAIDs) is included. During the post-trigger window (one through 30 days following discharge from the hospital), immediate post-operative complications (e.g. pneumonia, hemorrhage, lymphadenitis) and related follow up care (e.g., pathology reports, office or clinic follow-up visits, routine imaging) are included.

The total episode spend is calculated by adding the amounts of all the individual claims included in the episode.

2.5 Episode Exclusions and Risk Factors

To ensure that episodes are comparable across patient panels, select risk factors and exclusions are applied before assessing PAP performance. In the context of episode design, risk factors are attributes or underlying clinical conditions that are likely to impact a patient's course of care and the spend associated with a given episode. Exclusions are attributes or clinical conditions that cannot be adequately risk adjusted and that indicate either a distinct patient journey or incomparably high or low episode spend. Examples of potential risk factors for the tonsillectomy episode include asthma, otitis media, and chronic sinusitis.

Risk factors are selected via a standardized and iterative risk-adjustment process based on Ohio-specific regression analysis that gives due consideration to clinical relevance, statistical significance, and other contextual factors. Based on the selected risk factors, each episode is assigned a risk score. The total episode spend and the risk score are used to arrive at an adjusted episode spend, which is the spend on which providers are compared to each other. Table 2 in the Appendix lists potential risk factors, and Exhibit 6 presents an analysis of these risk factors. Note that the final list of risk factors will be determined after feedback from providers and the application of the statistical process described above.

By contrast, an episode is excluded from a patient panel when the patient has clinical factors that suggest he or she has experienced a distinct or different journey and/or that drive very significant increases in spend relative to the average patient. In addition, there are several "business-related" exclusions relating to reimbursement policy (e.g., whether a patient sought care out of state), the completeness of spend data for that patient (e.g., third-party liability or dual eligibility), and other topics relating to episode design and implementation, such as overlapping episodes, during the comparison period. Episodes with no exclusions are known as "valid" and used for provider comparisons. Episodes that have one of any of the exclusions are known as "invalid" episodes.

For the tonsillectomy episode, both business and clinical exclusions apply. Several of the business and clinical exclusions are standard across most episodes, while others are specific to this tonsillectomy episode. A history of peritonsillar abscess, relevant rare genetic disorders such as Down syndrome, and age younger than 6 months or

older than 20 years are currently implemented as exclusions. The final list of exclusions will be determined based on feedback from providers and the risk-adjustment process. A list of business and clinical exclusions is in Table 3, and analysis of these exclusions is in Exhibit 7 in the Appendix.

2.6 Quality Metrics

To ensure the episode model incentivizes quality care, the tonsillectomy episode has select quality metrics. These are calculated for each PAP meeting the minimum threshold for valid episodes.

The tonsillectomy episode has five proposed quality metrics. Two are linked to performance assessment, meaning that performance thresholds on these metrics must be met for the episodes to be eligible for positive incentive payments within the episode model. The specific threshold amount will be determined during the informational reporting period. Three of the quality metrics are for informational purposes only. The metrics tied to positive incentive payments are dexamethasone administration rate and the percentage of episodes with post-operative bleeding up to two days following the procedure. Informational metrics include the rate of indicated concurrent tympanostomy (where an indicated tympanostomy is performed on a patient 4 years or older with a history of recurrent otitis media), the rate of post-operative follow-up visits, and bleeding rate between the 3rd and 14th day. A detailed description of all five quality metrics is in Table 4, and analysis of these quality metrics is in Exhibit 8 in the Appendix.

3. APPENDIX: SUPPORTING ANALYSES

Table 1 – Episode triggers

Trigger category	Trigger codes (CPT)	Description
Tonsillectomy	42825	Tonsillectomy, primary or secondary; younger than age 12
	42826	Tonsillectomy, primary or secondary; age 12 or over
Adenoidectomy	42830	Adenoidectomy, primary; younger than age 12
	42831	Adenoidectomy, primary; age 12 or over
	42835	Adenoidectomy, secondary; younger than age 12
	42836	Adenoidectomy, secondary; age 12 or over
Tonsillectomy and adenoidectomy	42820	Tonsillectomy and adenoidectomy; younger than age 12
	42821	Tonsillectomy and adenoidectomy; age 12 or over

Table 2 – Episode risk factors

Risk factor	Relevant time period
Asthma	During the episode window and 365 days before the episode window
Chronic Sinusitis	During the 365 days before the episode window
Hearing Loss	During the episode window and 365 days before the episode window
Obesity	During the episode window and 365 days before the episode window
Allergic reactions	During the episode window and 365 days before the episode window
Diabetes with complications (e.g., retinopathy, neuropathy, etc.)	During the episode window and 365 days before the episode window
Epilepsy	During the episode window and 365 days before the episode window
Nutritional deficiencies	During the episode window and 365 days before the episode window
Other upper respiratory diseases	During the episode window and 365 days before the episode window
Respiratory failure	During the episode window and 365 days before the episode window
Sickle cell	During the episode window and 365 days before the episode window

Risk factor	Relevant time period
Bleeding disorders	During the episode window and 365 days before the episode window
Indicated tympanostomy (e.g., recurrent otitis media)	During 365 days before the episode window
Borderline personality disorder (BPD)	During the episode window and 365 days before the episode window
Diseases Of Esophagus	During the episode window and 365 days before the episode window
Genetic disorders	During the episode window and 365 days before the episode window
Immune disorders	During the episode window and 365 days before the episode window

Table 3 – Episode exclusions

Exclusion type	Episode exclusion	Description	Relevant time period
Business exclusion	Out of state	PAP operates out of state	N/A
	No PAP	An episode is excluded if the PAP cannot be identified	During the episode window
	Enrollment	Patient is not enrolled in Medicaid	During the episode window
	Third party liability	An episode is excluded if third-party liability charges are present on any claim or claim detail line or if the patient has	During the episode window

Exclusion type	Episode exclusion	Description	Relevant time period
		relevant third-party coverage at any time	
	Multi Payer	An episode is excluded if a patient changes enrollment between FFS and an MCP or between MCPs	During the episode window
	Dual	An episode is excluded if the patient had dual coverage by Medicare and Medicaid	During the episode window
	No DRG	An episode is excluded if a DRG-paid inpatient claim is missing the APR-DRG and severity of illness	During the episode window
	Left Against Medical Advice	Patient has discharge status of "left against medical advice"	During the episode window
	Death	An episode is excluded if the patient has a discharge status of "expired" on any inpatient or outpatient claim	During the episode window
	Long Admission	An episode is excluded if the patient has one or more hospital admissions for a duration greater than 30 days	During the episode window
	Long Term Care	An episode is excluded if the patient has one or	During the episode window

Exclusion type	Episode exclusion	Description	Relevant time period
		more long-term care claim detail lines which overlap the episode window	
Standard clinical exclusion	Cancer Treatment	Patient has diagnosis of cancer and procedures for active management of cancer	During the episode or up to 90 days before the start of the episode
	ESRD	Patient has diagnosis or procedure for end stage renal disease	During the episode or up to 365 days before the start of the episode
	Cystic Fibrosis	Patient has diagnosis of cystic fibrosis during the episode	During the episode or up to 365 days before the start of the episode
	Multiple Sclerosis	Patient has diagnosis of multiple sclerosis	During the episode window or during 365 days before the start of the episode
	Coma	Patient has diagnosis of coma during the episode	During the episode or up to 365 days before the start of the episode
	Transplant	An episode is excluded if a	During the episode or

Exclusion type	Episode exclusion	Description	Relevant time period
		patient has an organ transplant	up to 365 days before the start of the episode
	Paralysis	Patient has diagnosis of paralysis	During the episode or up to 365 days before the start of the episode
Episode-specific clinical exclusion	Age	Patient is older than 21 years or younger than 6 months	During the episode window
	Inpatient admission	Patient is admitted into an inpatient setting	During the trigger window
	Severe immune disorders	Patient has diagnosis of a severe immune disorder	During the episode or up to 365 days before the start of the episode
	Down syndrome	Patient is diagnosed with Down syndrome	During the episode or up to 365 days before the start of the episode
	Oral or pharyngeal cancer	Patient has diagnosis of oral or pharyngeal cancer	During the episode or up to 365 days before the start of the episode
	Muscular dystrophy	Patient has diagnosis of muscular dystrophy	During the episode or up to 365

Exclusion type	Episode exclusion	Description	Relevant time period
			days before the start of the episode
	Peritonsillar abscess	Patient has a peritonsillar abscess	Up to 365 days before the start of the episode
	Aspiration pneumonitis	Patient has a diagnosis of aspiration pneumonitis	Up to 365 days before the start of the episode
	Congestive heart failure	Patient has a diagnosis of congestive heart failure	During the episode or up to 365 days before the start of the episode
	Embolism	Patient has an embolism	Up to 365 days before the start of the episode
	Hypertension with complications	Patient has a diagnosis of hypertension with complications	During the episode or up to 365 days before the start of the episode
	Intrauterine hypoxia	Patient has a diagnosis of intrauterine hypoxia	During the episode or up to 365 days before the start of the episode

Exclusion type	Episode exclusion	Description	Relevant time period
	Lung disease due to external agents	Patient has a diagnosis of lung disease due to an external agent	During the episode or up to 365 days before the start of the episode
	Meningitis	Patient has a diagnosis of meningitis	Up to 365 days before the start of the episode
	Ill-defined cerebrovascular disease	Patient has a diagnosis of an ill-defined cerebrovascular disease	During the episode or up to 365 days before the start of the episode
	Pancreatic disorders	Patient has a diagnosis of a pancreatic disorder	During the episode or up to 365 days before the start of the episode
	Thrombophlebitis	Patient has a diagnosis of thrombophlebitis	Up to 365 days before the start of the episode
	Tuberculosis	Patient has a diagnosis of tuberculosis	During the episode or up to 365 days before the start of the episode
	Drowning	Patient has a diagnosis of drowning	During the episode or up to 365 days

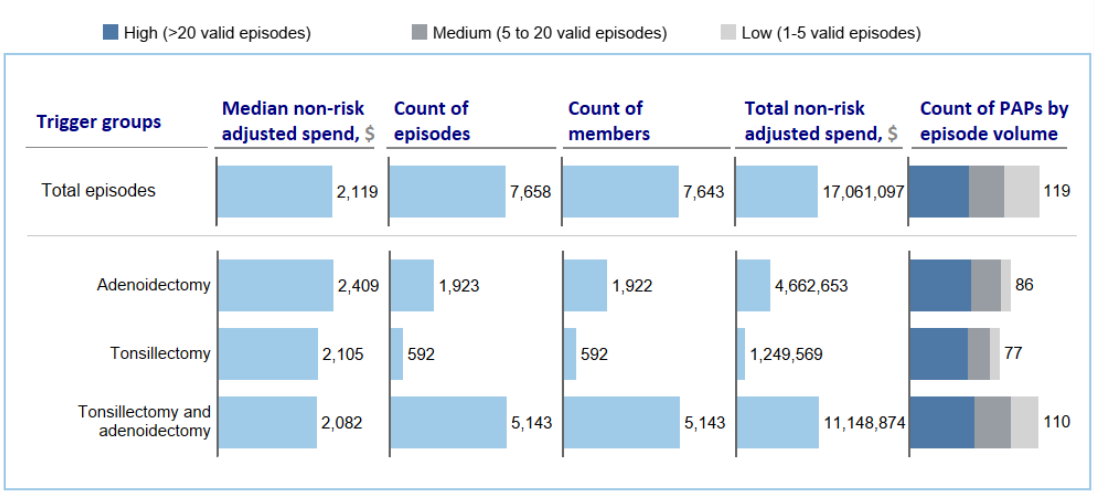
Exclusion type	Episode exclusion	Description	Relevant time period
			before the start of the episode
	Respiratory distress syndrome	Patient has a diagnosis of respiratory distress syndrome	Up to 365 days before the start of the episode
	Shock	Patient has a diagnosis of shock	Up to 365 days before the start of the episode

Table 4 – Episode quality metrics (PAP level)

Metric type	Quality metric	Description	Relevant time period
Tied to incentive payments	Dexamethasone administration rate	Percentage of valid episodes with dexamethasone administered during the trigger window among episodes triggered in an outpatient setting (higher rate indicative of better performance)	During the episode window
Tied to incentive payments	Bleeding up to two days following the procedure	Percentage of valid episodes with post-operative bleeding during the trigger window and up to two days afterward (lower rate indicative of better performance)	During the episode window

Informational	Rate of indicated concurrent tympanostomy	Percentage of valid episodes with tympanostomy concurrent with adenoidectomy for children with history of recurrent otitis media among patients who are four years of age and above (higher rate indicative of better performance)	During the episode window
Informational	Post-operative encounter rate	Percentage of valid episodes with post-operative encounter during the post-trigger window (lower rate indicative of better performance)	During the episode window
Informational	Bleeding rate between the 3rd and 14th day	Percentage of valid episodes with post-operative bleeding between the 3rd day and the 14th day (inclusive) after the trigger window (lower rate indicative of better performance)	During the episode window

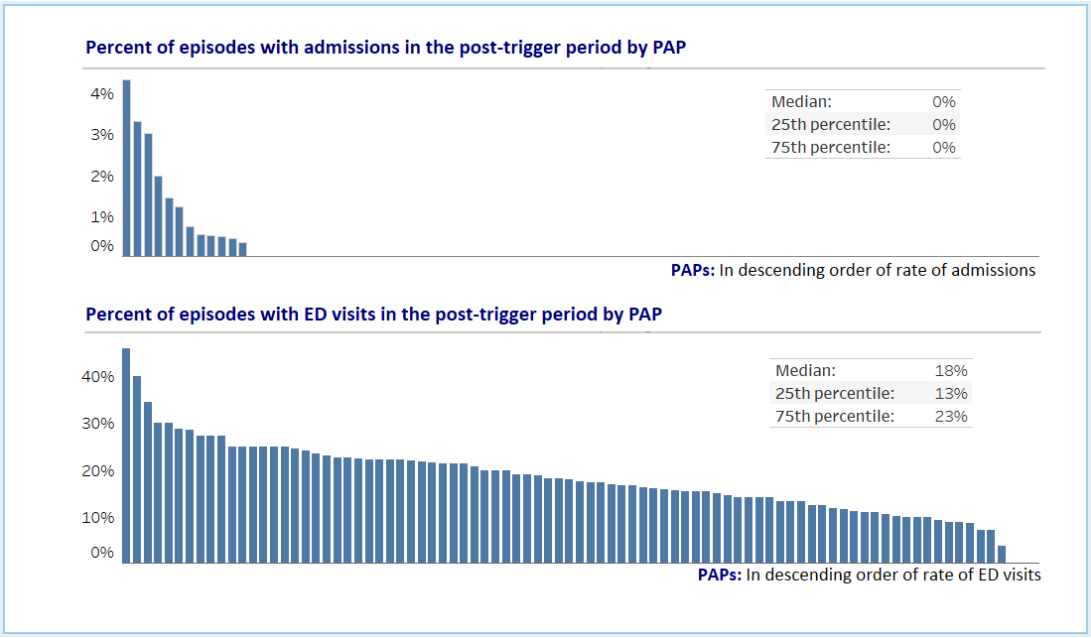
EXHIBIT 3 – TONSILLECTOMY AND ADENOIDECTOMY TRIGGER GROUPS[1]



1 For valid episodes (7,658) across all PAPs; valid episodes do not include those with business (e.g., third-party liability, dual eligibility) or clinical exclusions (e.g., cancer, ESRD)

SOURCE: OH claims data with episodes ending between 01/01/2014 and 12/31/2014

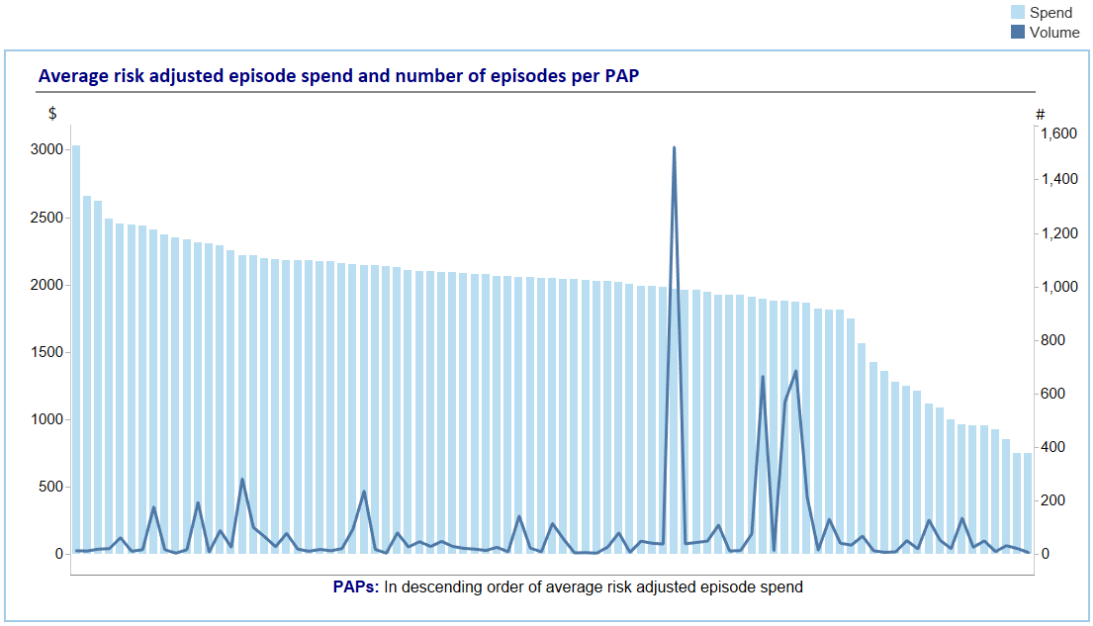
EXHIBIT 4 – VARIATION IN POST-TRIGGER ADMISSION AND ED VISIT RATES BY PAP[1]



1 For valid episodes (7,601) across PAPs with 5 or more valid episodes (87); valid episodes for PAPs with 4 or less episodes are not included in this analysis; valid episodes do not include those with business (e.g., third-party liability, dual eligibility) or clinical exclusions (e.g., cancer, ESRD). 75 PAPs have zero episodes with admissions in the post-trigger period and 3 PAPs have zero episodes with ED visits in the post-trigger period.

SOURCE: OH claims data with episodes ending between 10/01/2014 and 09/30/2015

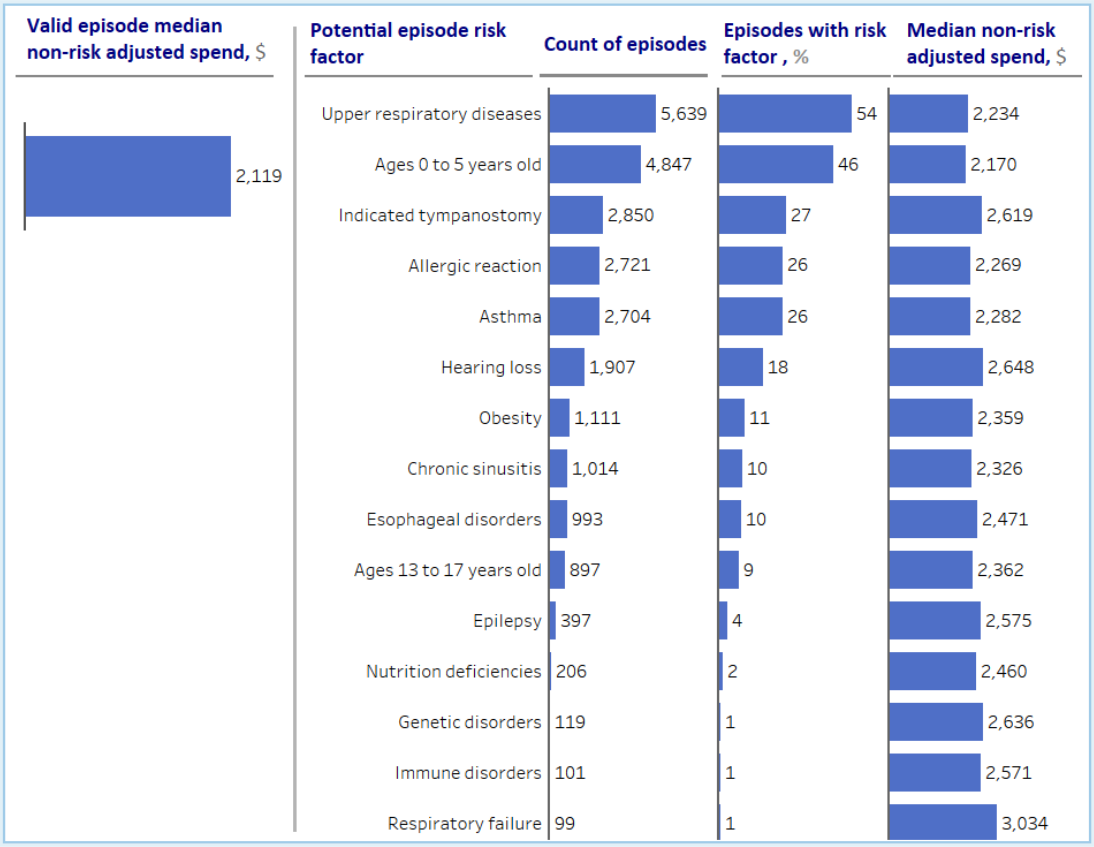
EXHIBIT 5 – DISTRIBUTION OF NON-RISK ADJUSTED AVERAGE EPISODE SPEND AND COUNT BY PAP[1]



1 For valid episodes (7,601) across PAPs with at least 5 valid episodes (87); valid episodes do not include those with business (e.g., third-party liability, dual eligibility) or clinical exclusions (e.g., cancer, ESRD)

SOURCE: OH claims data with episodes ending between 10/01/2014 and 09/30/2015

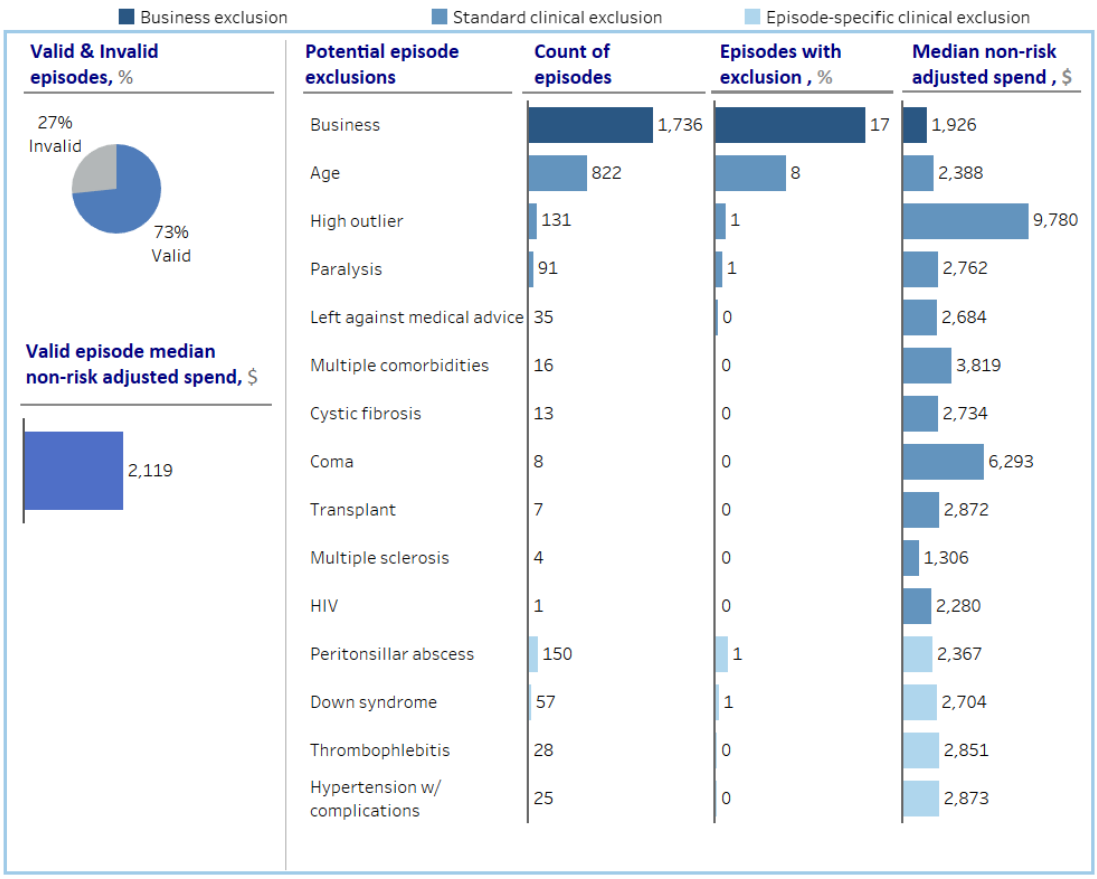
EXHIBIT 6 – EPISODE COUNT AND SPEND BY POTENTIAL EPISODE RISK FACTOR[1]



1 Showing the all factors that were statistically significant in the risk model for this episode; 7,658 valid episodes across all PAPs; valid episodes do not include those with business (e.g., third-party liability, dual eligibility) or clinical exclusions (e.g., cancer, ESRD)
2 For episodes with this potential risk factor; one episode can have multiple risk factors

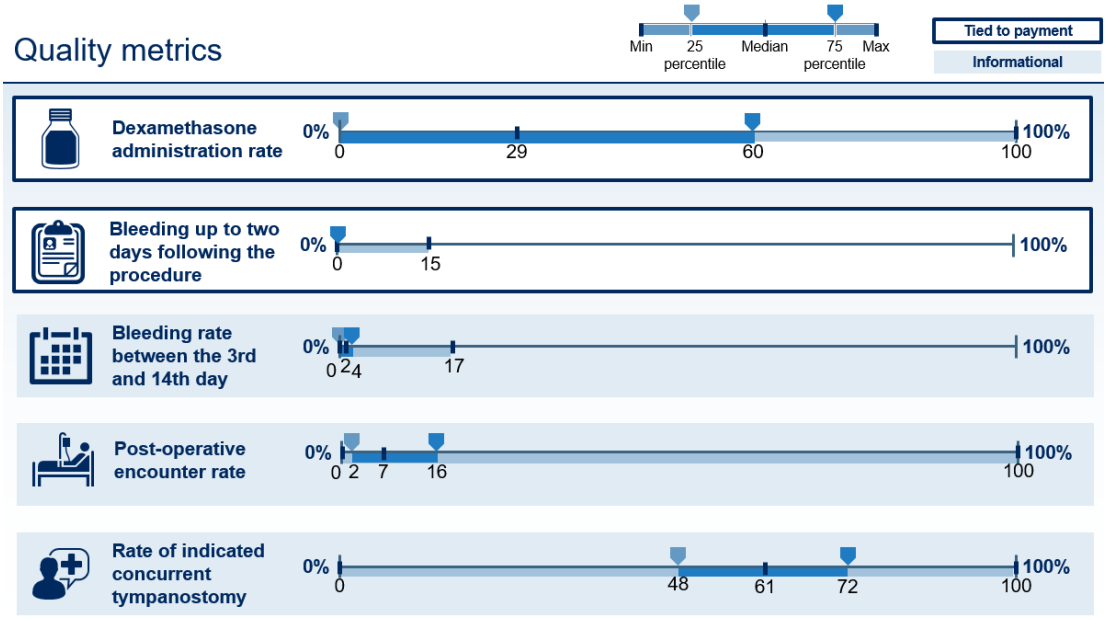
SOURCE: OH claims data with episodes ending between 10/01/2014 and 09/30/2015

EXHIBIT 7 – EPISODE COUNT AND SPEND BY POTENTIAL EPISODE EXCLUSION[1]



1 Showing a select number of potential exclusions
2 For episodes with this potential exclusion; one episode can have multiple exclusions
SOURCE: OH claims data with episodes ending between 10/01/2014 and 09/30/2015

EXHIBIT 8 - PAP PERFORMANCE ON PROPOSED EPISODE QUALITY METRICS[1]



1 For valid episodes (7,601) across PAPs with 5 or more valid episodes (87); valid episodes for PAPs with 4 or less episodes are not included in this analysis; valid episodes do not include those with business (e.g., third-party liability, dual eligibility) or clinical exclusions (e.g., cancer, ESRD)

SOURCE: OH claims data with episodes ending between 10/01/2014 and 09/30/2015