Washington State Health Care Authority
Health Technology Assessment

Imaging for Rhinosinusitus

Clinical Expert

Amy Anstead, MD

Director of Rhinology and Endoscopic Skull Base Surgery
Virginia Mason Medical Center

Disclosure

Any unmarked topic will be considered a "Yes"

	Potential Conflict Type	Yes	No
1.	Salary or payments such as consulting fees or honoraria in excess of $10,000.		/
2.	Equity interests such as stocks, stock options or other ownership interests.		/
3.	Status or position as an officer, board member, trustee, owner.		/
4.	Loan or intellectual property rights.		/
5.	Research funding.		/
6.	Any other relationship, including travel arrangements.		/

If yes, list name of organizations that relationship(s) are with and for #6, describe other relationship:

	Potential Conflict Type	Yes	No
7.	Representation: if representing a person or organization, include the name and funding sources (e.g. member dues, governmental/taxes, commercial products or services, grants from industry or government).		/

If yes to #7, provide name and funding Sources:

*If you believe that you do not have a conflict, but are concerned that it may appear that you do, you may **attach additional sheets** explaining why you believe that you should not be excluded.*

I certify that I have read and understand this Conflict of Interest form and that the information I have provided is true, complete, and correct as of this date.

X [redacted] 4/20/15 A. ANSTEAD MD

Signature *Date* *Print Name*

So we may contact you regarding this information, please provide the following:

Email Address: AMY.ANSTEAD@UMMC.ORG

Phone Number: [redacted]

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Director of Rhinology and Endoscopic Skull Base Surgery
Virginia Mason Medical Center
Mailstop X10-ON 1100 9th Ave. PO Box 900
Seattle, WA 98111 (206) 341-1395
amy.anstead@vmmc.org

Education, Training & Employment

Director, Rhinology and Endoscopic Skull Base Surgery 2010-present
Department of Otolaryngology – Head and Neck Surgery
Virginia Mason Medical Center Seattle, WA

Board Certified by the Academy of Otolaryngology – Head and Neck Surgery 2010

University of Miami, Florida 7/2009-7/2010
Clinical Instructor and Fellow in Rhinology – Endoscopic Skull Base Surgery
With Dr. Roy Casiano

University of Illinois, Chicago Eye and Ear Infirmary 7/2004-6/2009
Otolaryngology – Head and Neck Surgery Resident 2005-2009
General Surgery Resident 2004-2005
In-service score: 98th-100th percentile each year
Resident Research Award – Honorable Mention 2007

University of Miami, FL School of Medicine 6/2000-5/2004
Alpha Omega Alpha Medical Honor Society Member
Doctor of Medicine 2004

Arizona State University 8/1993-8/1998
Bachelor of Science Microbiology, August 1998
Bachelor of Science Psychology, August1998

Licensure & Board Certification

2010-Present Diplomate of the American Board of Otolaryngology
2010-Present Washington State Medical License
2008-Present Florida State Medical License (#ME103066)
2008-Present DEA License (FA1258210)
2008-Present Diplomate of the National Board of Medical Examiners

Membership

- Alpha Omega Alpha Medical Honor Society Member
- American Rhinologic Society
- North American Skull Base Society
- American Academy of Otolaryngology – H&N Surgery
- Triological Society

- Washington State Medical Association
- American Medical Association
- King County Medical Society
- Northwest Academy of Otolaryngology

Honors and Awards

- 2014 Top Doctors Seattle Met Magazine
- 2013 Top Doctors Seattle Met Magazine
- 2007 Resident Research Award – Honorable Mention
- 2003 Alpha Omega Alpha Medical Honor Society Election

Research Publications

- "Modified subtotal Lothrop procedure for extended frontal sinus and anterior skull base access: a cadaveric feasibility study with clinical correlates." *Journal of Neurologic Surgery and Skull Base*, Eloy JA, Liu JK, Choudhry OJ, Anstead AS, Tessema B, Folbe AJ, Casiano RR. 2013 Jun;74(3):130-5. doi: 10.1055/s-0033-1338264. Epub 2013 Mar 15.
- "The effect of head position on the distribution of topical nasal medication using the mucosal Atomization Device: A cadaver study." Habib AR, Thamboo A, Manji J, Dar Santos RC, Gan EC, Anstead A, Javer AR. *International Forum Allergy Rhinology* 2013 Dec;3(12):958-62. doi: 10.1002/alr.21222. Epub 2013 Sep 16
- "Coblation assisted endoscopic juvenile nasopharyngeal angiofibroma resection" *International Journal of Pediatric Otolaryngology*, 2012Mar;76(3):439-42. Ruiz, JW, Saint-Victor S, Tessema B, Eloy JA, Anstead A
- "Endoscopic Management of sinonasal hemangiopericytoma" *Otolaryngology Head and Neck Surgery* 2012 March; 146(3):483-6. Tessema B, Eloy JA, Folbe AJ, Anstead AS, Mirani NM, Joudy DN, Ruiz JW, Casiano RR.
- "Botulinum Toxin A Can Positively Impact First Impressions", *Dermatologic Surgery* June 2008; 34:S40-S47 Stephen Dayan MD and Amy Anstead MD
    - Accepted for poster presentation at the 9/2008 Academy meeting in Chicago *Otolaryngology - Head and Neck Surgery*, Volume 139, Issue 2
- "Obstructive Sleep Apnea and PICU Admissions after Adenotonsillectomy" *International Journal of Pediatric Otorhinolaryngology*, Volume 73, Issue 8, Pages 1095-1099 Jim Schroeder MD and Amy Anstead MD
    - Accepted for oral presentation at 9/2008 Academy meeting in Chicago

Book Chapters Published

- "Basic Endoscopic Sinonasal Dissection**"** by Roy Casiano MD and Amy Anstead MD in *Endoscopic Sinonasal Dissection Guide* by Roy Casinao 2010
- "Advanced Endoscopic Sinonasal Dissection**"** by Roy Casiano MD and Amy Anstead MD in *Endoscopic Sinonasal Dissection Guide* by Roy Casinao 2010
- **"**Minimally Invasive Surgical Options for Anterior Cranial Fossa Tumors" by Roy Cassiano MD and Amy Anstead MD to be published in *Minimally Invasive Surgery of the Head and Neck* by Peter Catalan MD 2010

- "Management of Malignant Head and Neck Tumors in Children" by John Maddalozzo, MD and Amy Anstead MD. *Practical Head and Neck Oncology*, Guy J. Petruzzelli MD 2008

Oral Presentations

- "Spectacular Cases in Rhinology" Seattle Otology and Advanced Rhinology Course; Seattle, WA 2015
- "Skull Base Defects" Seattle Otology and Advanced Rhinology Course; Seattle, WA 2015
- "CT Anatomy of the Paranasal Sinuses and Preoperative Evaluation" Endoscopic Sinonasal and Skull Base Anatomy and Surgical Techniques Course, Seattle, WA 2014
- "Advanced frontal sinus approaches including modified Lothrop" Endoscopic Sinonasal and Skull Base Anatomy and Surgical Techniques Course, Seattle, WA 2014
- "Endoscopic Anterior Skull Base Resection" Endoscopic Sinonasal and Skull Base Anatomy and Surgical Techniques Course, Seattle, WA 2014
- "Doctor, Why didn't my sinus surgery work?" American Rhinologic Society Summer Sinus Symposium 2014
- "Vascular Anatomy of the Nose, Sinuses and Skull Base: Management of Epistaxis and Vascular injuries" Endoscopic Sinonasal and Skull Base Anatomy and Surgical Techniques Course; West Palm Beach, FL 2014
- "Selecting your approach to the frontal sinus: from balloons to Drills" American Rhinologic Society Summer Sinus Symposium 2013
- "Boogers and other sinonasal maladies" Virginia Mason Medical Center Grand Rounds, Seattle, WA 2013
- "Advanced frontal sinus approached including modified Lothrop" Endoscopic Sinonasal and Skull Base Anatomy and Surgical Techniques Course, Seattle, WA 2012
- "Endoscopic Anterior skull base resection" Endoscopic Sinonasal and Skull Base Anatomy and Surgical Techniques Course, Seattle, WA 2012
- "Advanced Rhinology Topics: Endoscopic skull base and pituitary surgery" UBC Current Techniques in Endoscopic Sinus Surgery. Vancouver, Canada 2012
- "What's new in sinusitis management" UBC Current Techniques in Endoscopic Sinus Surgery. Vancouver, Canada 2012
- "Panel: Interesting cases" UBC Current Techniques in Endoscopic Sinus Surgery. Vancouver, Canada 2012
- "CT Anatomy of the Paranasal Sinuses and Preoperative Evaluation" Endoscopic Sinonasal and Skull Base Anatomy and Surgical Techniques Course, Seattle, WA 2011
- "Clival and Periclival Neoplasms" Endoscopic Sinonasal and Skull Base Anatomy and Surgical Techniques Course, Seattle, WA 2011
- "Management of Chronic Sinusitis" Alaska Family Physician Annual meeting Seward, AK 2011

- "Chronic Sinusitis" Washington State Medical Assistants Association Annual Conference Tacoma, WA 2011
- "Endoscopic Anterior Skull Base Resection," Grand Rounds at the University of Washington, Seattle 2011
- "Orbital and Optic Nerve Decompression and Management of Orbital Complications" Endoscopic Sinonasal and Skull Base Anatomy and Surgical Techniques Course; West Palm Beach, FL 2011
- "Endoscopic Anterior Skull Base Resection" Virginia Mason Otolaryngology Updates Course. Seattle, WA 2010
- "Management of unilarteral skull base tumors with endoscopic hemi-anterior skull base resection," with Dr. Roy Casiano American Rhinologic Society meeting Boston, MA 2010
- "Endoscopic management of Clival tumors," Grand Rounds University of Miami, FL 2010
- "Trends in Systemic Steroid Use in Chronic Rhinosinusitis" Amy Anstead MD and Stephanie Joe MD; 4/2009 RhinoWorld in Philadelphia, PA
- "Sinonasal Tumors" Amy Anstead MD Grand Rounds University of Illinois, Chicago 11/2008
- "Obstructive Sleep Apnea and PICU Admissions after Adenotonsillectomy" Amy Anstead MD and Jim Schroeder MD; 9/2008 American Academy of Otolaryngology meeting in Chicago, IL
- "Nasalseptal Flap Dimensions and Blood Supply" Resident Research Day Presentation. University of Illinois, Chicago 2008
- "Melanoma of the Head and Neck", Department of Otolaryngology – Head and Neck Surgery Grand Rounds, University of Illinois at Chicago 2007
- "Obstructive Sleep Apnea and PICU Admissions after Adenotonsillectomy" Resident Research Day Presentation. University of Illinois, Chicago 2007
- "Skin Grafting", Department of Otolaryngology – Head and Neck Surgery Grand Rounds, University of Illinois at Chicago 2006
- "Safety of Open Septorhinoplasty with Autogenous Costal Cartilage" Resident Research Day Presentation University of Illinois, Chicago 2006
- "Pediatric Neck Masses" Department of Otolaryngology – Head and Neck Surgery Grand Rounds, University of Illinois at Chicago 2006

Poster Presentations

- "Edoscopic Assisted Removal of Anterior Skull Base Fibrosarcoma using the Sonopet Ultrasonic Bone Aspirator," John Wood MD, Amy Anstead MD, Lori Lemmonier MD, Roy Casiano; presented at the North American Skull Base Society meetin in Scottsdale, AZ 2010
- "Botulinum Toxin A Can Positively Impact First Impressions", *Dermatologic Surgery* June 2008; 34:S40-S47 Stephen Dayan MD and Amy Anstead MD presented at the 9/2008 Academy meeting in Chicago *Otolaryngology - Head and Neck Surgery,* Volume 139, Issue 2

CME Courses Directed or Instructed

- Seattle Otology and Advanced Rhinology Course; Seattle, WA 2015 Instructor
- Endoscopic Sinonasal & Skull Base Anatomy and Surgical Techniques Course at Virginia Mason Medical Center, Seattle WA 2014, Co- Director and Instructor
- Seattle Otology and Advanced Rhinology Course; Seattle, WA 2014 Instructor
- Endoscopic Sinonasal and Skull Base Anatomy and Surgical Techniques Course; West Palm Beach, FL 2013 Instructor
- Endoscopic Sinonasal & Skull Base Anatomy and Surgical Techniques Course at Virginia Mason Medical Center, Seattle WA 2012, Co- Director and Instructor
- Current Techniques in Endoscopic Sinus Surgery, University of British Columbia, Vancouver, BC Canada 2012 Instructor
- Virginia Mason Updates in Otolaryngology Course. Seattle, WA 2012 Instructor
- Endoscopic Sinonasal & Skull Base Anatomy and Surgical Techniques Course at Virginia Mason Medical Center, Seattle WA 2011, Co- Director and Instructor
- Endoscopic Sinonasal and Skull Base Anatomy and Surgical Techniques Course; West Palm Beach, FL 2011 Instructor
- Virginia Mason Otolaryngology Updates in Otolaryngology Course. Seattle, WA 2010 Instructor

Editorial Positions

- Reviewer, Otolaryngology – Head and Neck Surgery
- Reviewer, American Journal of Rhinology & Allergy
- Reviewer, Laryngoscope

Medical School Experience

- Alpha Omega Alpha (AOA) Member 2003
- Iota Epsilon Alpha Medical Honor Society 2000
- Gross Anatomy Teaching Assistant, Head and Neck 2004
- Florida Keys Health Fair 2003
- Alder-Everitt Academic Society 2002-2004
- Hospital General De Granollers Oncology, Radiology and Pediatrics Clerkships, Spain 2002
- ESADE (La Escuela Superior de Administracion y Direccion de Empresas) Escuela De Idiomas, Language Student, Barcelona, Spain 2001-2002
- Anatomy Elective, Dissection Specialist, 2000
- American Red Cross, Volunteer/Instructor 1991-2004

References

R. Casiano MD Professor and Vice Chair U of Miami, FL rcasiano@med.miami.edu
Dean Toriumi MD Professor University of Illinois, Chicago dtoriumi@uic.edu
Rakhi Thambi MD University of Illinois, Chicago rthambi@uic.edu
H. Steven Sims MD University of Illinois, Chicago hssims@uic.edu
More references available upon request

Outside Activities

- Chicago Half Marathon 2007
- Nashville Half Marathon 2007
- PADI Open Water Diver Certified, Key Largo, FL 2007
- 2nd Place, Member of Hospital General de Granollers Women's Running Team in 5K Catalan Inter-hospital run in Barcelona, Spain 2002
- 6th Fastest Woman in the West Indies, West Indies 2 mile Cross Bay Swim, St. George's, Grenada, W.I. 1999
- Conversational in Spanish

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Agency Medical Director Comments

Imaging for Rhinosinusitus

Charissa Fotinos, MD, MSc
Deputy Chief Medical Officer
Washington State Health Care Authority

May 15, 2015

Agency Medical Director Concerns

- **Safety = Medium**
- **Efficacy = High**
- **Cost = Medium**

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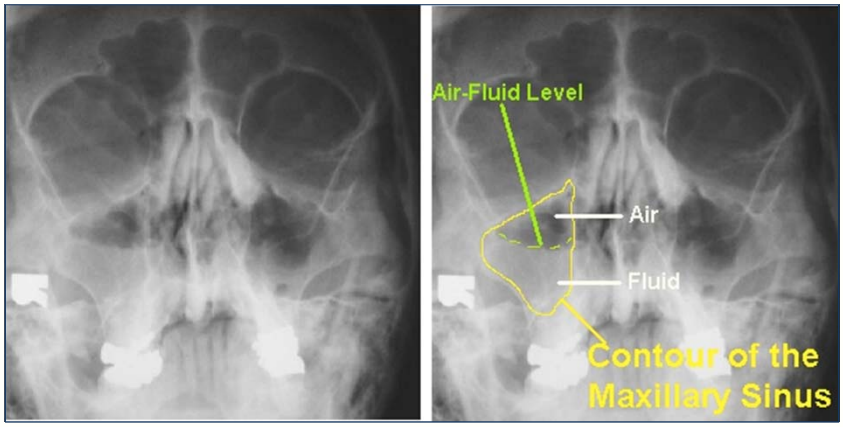
Imaging for Rhinosinusitus

Plain X-ray



http://www.ghorayeb.com/ImagingMaxillarySinusitis.html

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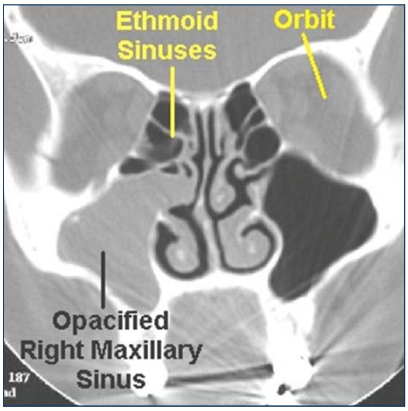
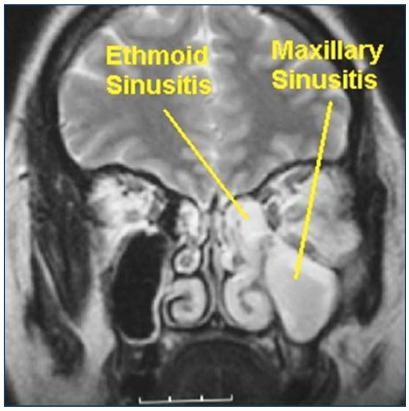
Imaging for Rhinosinusitus

CT



MRI



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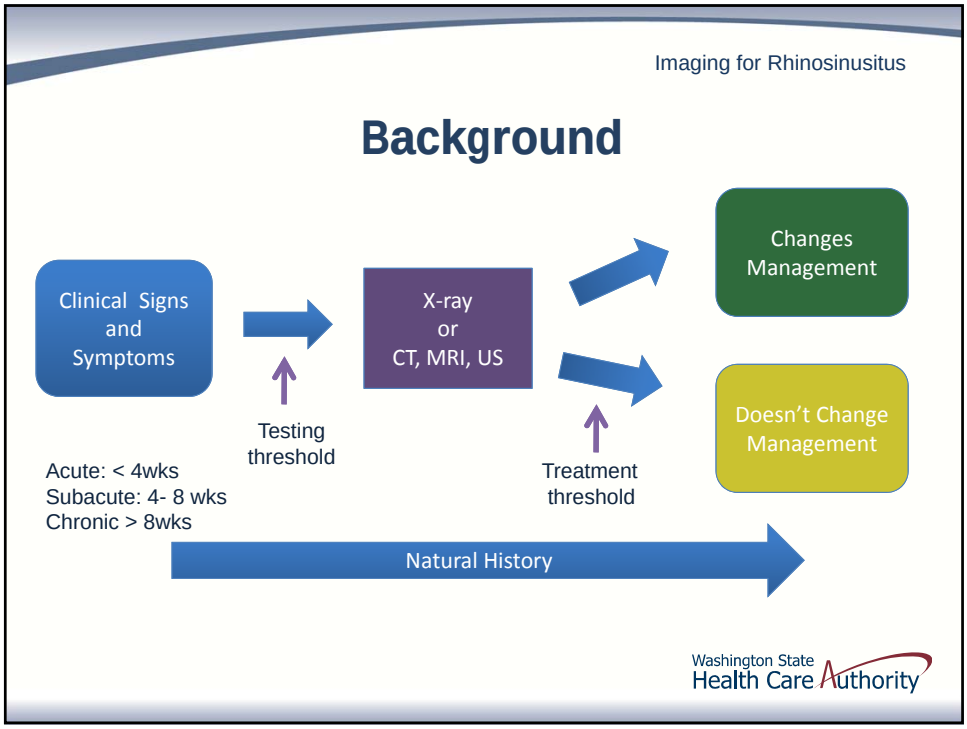
Imaging for Rhinosinusitus
Background
Clinical Signs and Symptoms
Testing threshold
X-ray or CT, MRI, US
Changes Management
Doesn't Change Management
Treatment threshold
Acute: < 4wks
Subacute: 4- 8 wks
Chronic > 8wks
Natural History
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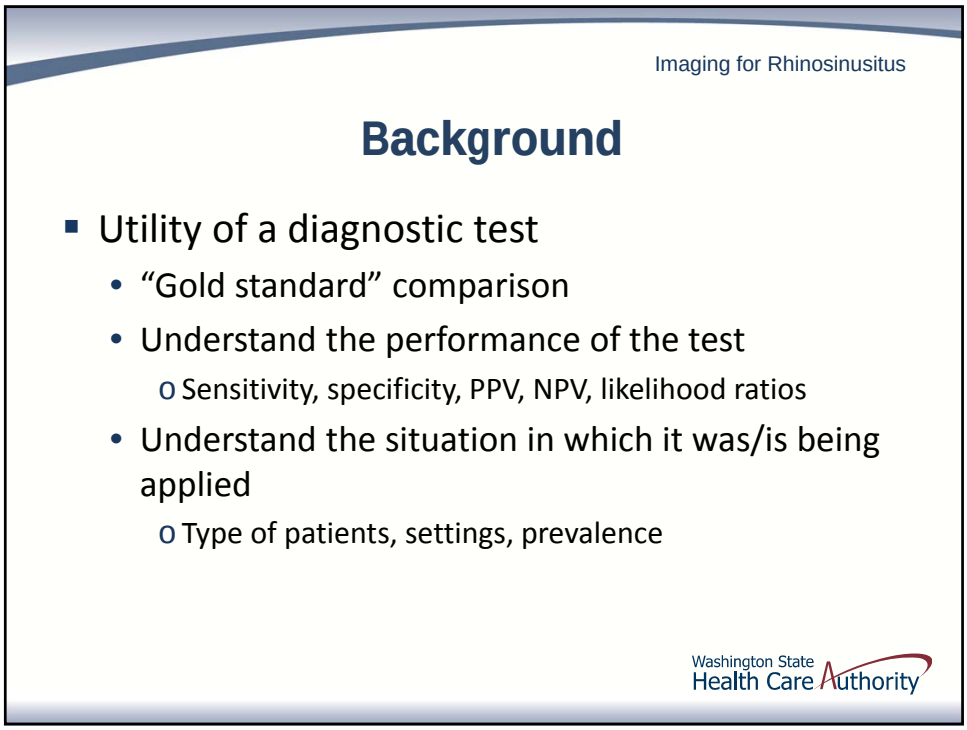
Imaging for Rhinosinusitus
Background
Utility of a diagnostic test
"Gold standard" comparison
Understand the performance of the test
Sensitivity, specificity, PPV, NPV, likelihood ratios
Understand the situation in which it was/is being applied
Type of patients, settings, prevalence
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Imaging for Rhinosinusitus

A Refresher

- Sensitivity
  - Proportion of people with the condition who have a positive test
- Specificity
  - Proportion of people without the condition who have a negative test
- Positive Predictive Value
  - Proportion of people who test positive that actually have the condition
- Negative Predictive Value
  - Proportion of people who test negative that do not have the condition

Characteristics of the test, fixed

Results vary with prevalence

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Refresher, continued

Likelihood ratio:

- LR+
  - The probability that a person who has the disease will test positive/The probability that a person without the disease will test positive
- LR-
  - The probability that a person who has the condition will test negative/The probability that a person without disease will test negative

Characteristics of the test, fixed

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2 Examples of Clinical Prediction Models for Acute Bacterial Rhinosinusitis

Williams	
Signs/ Symptoms	**Positive Likelihood Ratio (LR+)**
Maxillary tooth pain	2.5
Antihistamines/ decongestants not helping	2.1
Purulent nasal D/C	2.1
Abnormal transillumination	1.6
Colored nasal D/C	1.5
> 4 together	**LR+ 6.4**

Berg	
Signs/ Symptoms	**PPV %**
Purulent rhinorrhea*	50
Local pain*	41
Pus in nasal cavity	17
Bilateral nasal purulence	15
*Primarily unilateral	
> 3 together	**LR+ 6.75**

Desrosiers et al. Allergy, Asthma & Clinical Immunology 2011, 7:2
http://www.aacijournal.com/content/7/1/2

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Treatment

Factor	Lowers Treatment Threshold	Raises Treatment Threshold
Safety of next test	Higher risk from tests	Low or zero risk
Costs of next test	More expensive tests	Lower costs of tests
Prognosis	Serious	Less serious
Effectiveness of treatment	Highly effective	Less effective
Safety of treatment	Low risk from treatment	Higher risk from treatment
Availability of treatment	Treatment available	Treatment less available

Guyatt G, et. al. User's Guide to the Medical Literature: 3rd Edition, 2014

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Imaging for Rhinosinusitus

View Test Results as Likelihood Ratios

- Positive and negative likelihood ratios were calculated for representative studies
- Assumptions
  - Pre and post-test probabilities using the LRs were calculated using the prevalence reported in the study
  - Additional probabilities with lower prevalence rates were also calculated
  - When there was a choice of two radiologists the higher specificities and sensitivities were used

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Imaging for Rhinosinusitus

Is Imaging Effective?

Author	Prev	PPV NPV	LR+ 95% CI	LR- 95% CI	Pre-test Prob	Post Test Prob +	 -
Burke X-ray vs. CT	72% All	93% 47%	5.17 (0.78-34)	0.43 (0.24-0.79)	**20%** 50% 72%	**56%** 84% 93%	10% 30% 53%
Aalokken X-ray vs CT	48% Max	90% 83%	10.0 (3.82-26)	0.22 (0.12-0.39)	**20%** 48%	**71%** 90%	**5%** 17%
Chronic							
Vento US vs. CT	25%	35% 77%	1.58 (0.68-3.66)	0.86 (0.62-1.18)	**25%** 50%	**34%** 61%	**22%** 46%
Timmenga X-ray vs. CT	65%	83% 69%	2.68 (1.16-6.16)	0.25 (0.09-0.64)	**20%** 65%	**40%** 83%	**6%** 32%
Fungal							
Lenglinger CT vs.Histo	71%	93% 83%	5.47 (0.94-32)	0.08 (0.01-0.56)	**20%** 50% 71%	**58%** 85% 93%	**2%** 7% 16%

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Imaging for Rhinosinusitus

Testing

Factor	Lowers Test Threshold	Raises Test Threshold
Test safety	Low or zero-risk test	Higher risk (invasive)
Test cost	Low-cost test	Higher cost
Test acceptability to patient	High acceptability	Lower acceptability
Prognosis of target disorder	Serious if not diagnosed	Less serious if missed
Effectiveness of treatment	Treatment effective	Treatment less effective
Availability of treatment	Treatment available	Treatment not available

Guyatt G, et. al. User's Guide to the Medical Literature: 3rd Edition, 2014

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Imaging for Rhinosinusitus

Radiation Exposures: Harms

Exposure Type	Millisievert (mSv)
Lowest Annual Dose at which increase in cancer is evident	100.00
CT scan: heart	16.00
CT scan: abdomen & pelvic	15.00
Dose of Full body CT scan	10.00
Annual airline crew exposure polar route NY to Tokyo	9.00
Natural exposure per year	2.00
CT: head	2.00
Spine X-ray	1.50
Mammogram	0.40
Chest X-ray	0.10
Dental X-ray	0.01

Sinus CT

0.1 – 1mSv

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Imaging for Rhinosinusitus

Recommendations of ACR for Acute Uncomplicated Rhinosinusitis

Clinical Condition: Sinonasal Disease

Variant 1: Acute (<4 weeks) or subacute (4-12 weeks) uncomplicated rhinosinusitis.

Radiologic Procedure	Rating	Comments	RRL*
CT paranasal sinuses without contrast	5	Most episodes are managed without imaging, as this is primarily a clinical diagnosis. Imaging may be indicated if acute frontal sphenoid sinusitis is suspected, or if there are atypical symptoms, or if the diagnosis is uncertain.	☢☢
MRI head and paranasal sinuses without contrast	4	May be useful as part of a general workup for headache.	O
MRI head and paranasal sinuses without and with contrast	2	May be useful as part of a general workup for headache.	O
CT paranasal sinuses with contrast	2		☢☢
CT paranasal sinuses without and with contrast	1		☢☢☢
X-ray paranasal sinuses	1		☢
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

American College of Radiology ACR Appropriateness Criteria 2009, Update 2012

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Imaging for Rhinosinusitus

ACR Imaging for Recurrent Acute or Chronic Sinusitis

Variant 4: Recurrent acute or chronic rhinosinusitis (possible surgical candidate).

Radiologic Procedure	Rating	Comments	RRL*
CT paranasal sinuses without contrast	9	Consider using as a surgical planning protocol.	☢☢
CT paranasal sinuses with contrast	4		☢☢
CT paranasal sinuses without and with contrast	3		☢☢☢
MRI head and paranasal sinuses without and with contrast	3		O
MRI head and paranasal sinuses without contrast	2		O
X-ray paranasal sinuses	1	May be indicated for planning frontal sinus obliteration.	☢
SPECT paranasal sinuses	1		☢☢☢
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

American College of Radiology ACR Appropriateness Criteria 2009, Update 2012

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Imaging for Rhinosinusitus

Red Flag Symptoms

- Altered mental status
- Severe headache
- Swelling of the orbit or visual changes
- Neurologic findings
- Signs of meningeal irritation
- Signs of intracranial complications:
  - Meningitis
  - Intracerebral abscess
  - Cavernous sinus thrombosis
- Involvement of nearby structures
  - Peri-orbital cellulits

Desrosiers et al. Allergy, Asthma & Clinical Immunology 2011, 7:2
http://www.aacijournal.com/content/7/1/2

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Imaging for Rhinosinusitus

Choosing Wisely

- Treating sinusitis: “Don’t rush to antibiotics”
- AAFP & AAAAI “antibiotics usually do not help sinus problems, cost money and have risks”
- Antibiotics after a week, double sickening, signs of severe infection.
- CT only if sinus problems often or considering surgery

http://www.choosingwisely.org/patient-resources/treating-sinusitis-aaaai/

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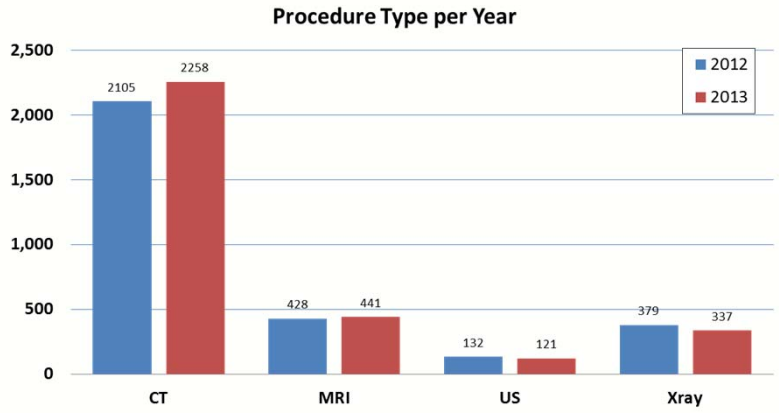
Imaging for Rhinosinusitus

PEBB/UMP Utilization Rates



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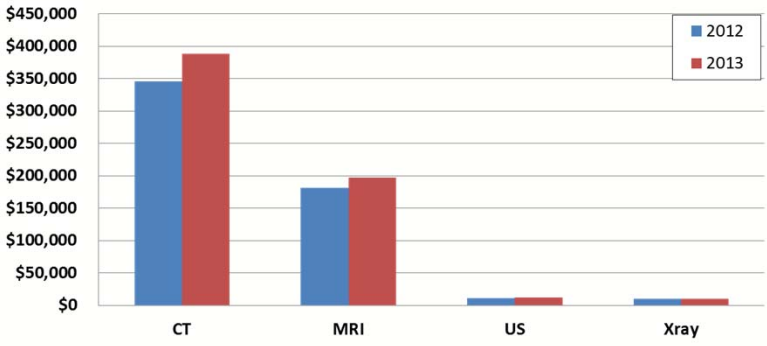
PEBB/UMP Costs



Year	CT	MRI	US	X-ray
2012	$345,523	$181,152	$11,182	$10,168
2013	$388,300	$197,150	$11,933	$9,854

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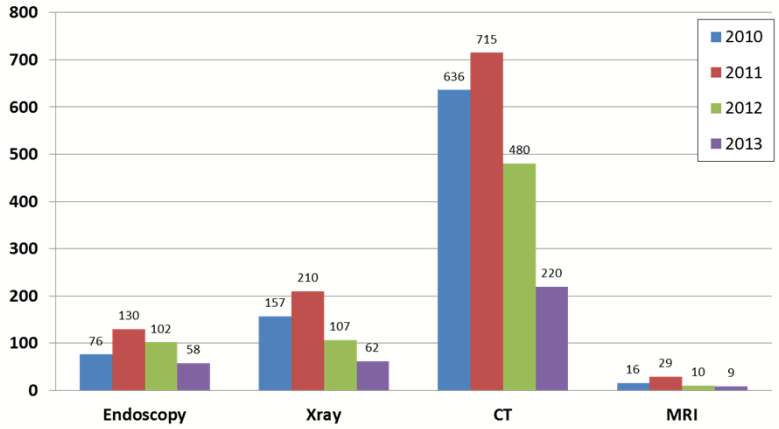
Medicaid FFS Utilization Rates & Costs

Number of Procedures for Medicaid



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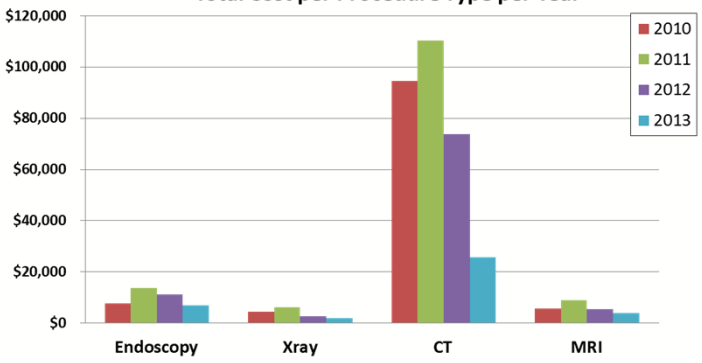
Medicaid FFS

Total Cost per Procedure Type per Year



	2010	2011	2012	2013
Procedure	REIMBURSED	REIMBURSED	REIMBURSED	REIMBURSED
Endoscopy	$7,738.83	$13,724.40	$11,133.05	$6,967.35
Xray	$4,543.16	$6,217.31	$2,672.02	$1,863.19
CT	$94,633.22	$110,267.91	$73,737.63	$25,807.73
MRI	$5,586.55	$8,913.76	$5,363.28	$3,964.70
Total	**$112,501.76**	**$139,123.38**	**$92,905.98**	**$38,602.97**

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Imaging for Rhinosinusitus

Current State Agency Policy

- **Medicaid** – FFS covers without conditions
- **PEBB** – Covers X-ray and US, CT and MRI require PA
- **Labor & Industries –** Covers X-ray and US, CT and MRI require PA
- **Dept. of Corrections –** Covers X-ray, CT, MRI and US require PA

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Imaging for Rhinosinusitus

Agency Medical Director Summary

- **For Acute Sinusitis**:
  - Difficult to distinguish between viral and bacterial, clinically and with imaging
  - Most cases of either type will resolve without intervention
  - X-ray identifies and rules out fewer cases than CT
  - CT scan changes can occur in asymptomatic patients and with URIs
  - There have not been studies testing CT against a 'gold standard'
  - Favorable positive predictive values are in part due to high prevalence rates

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Agency Medical Director Summary

- **For Chronic Sinusitis:**
  - + LRs for X-ray and US are low and not helpful in low prevalence settings
  - Questionable utility of CT in this setting unless planning for surgery or concern for complications
- **Chronic Fungal Sinusitis:**
  - CT in this setting has a higher +LR and is more useful to rule in or out the diagnosis
- **Cost Effectiveness:**
  - Three modeling and one clinical study suggesting CT is cost effective if not preceded by nasopharyngoscopy

Washington State Health Care Authority

Agency Recommendation

Acute Sinusitis and Chronic Sinusitis:

- X-ray: Do Not Cover
- CT scan: Cover w/conditions
  - Acutely ill or red flags
  - Concern for complications
  - Surgical planning
- US: consider coverage in pregnancy
- MRI: cover only by Specialist and w/PA

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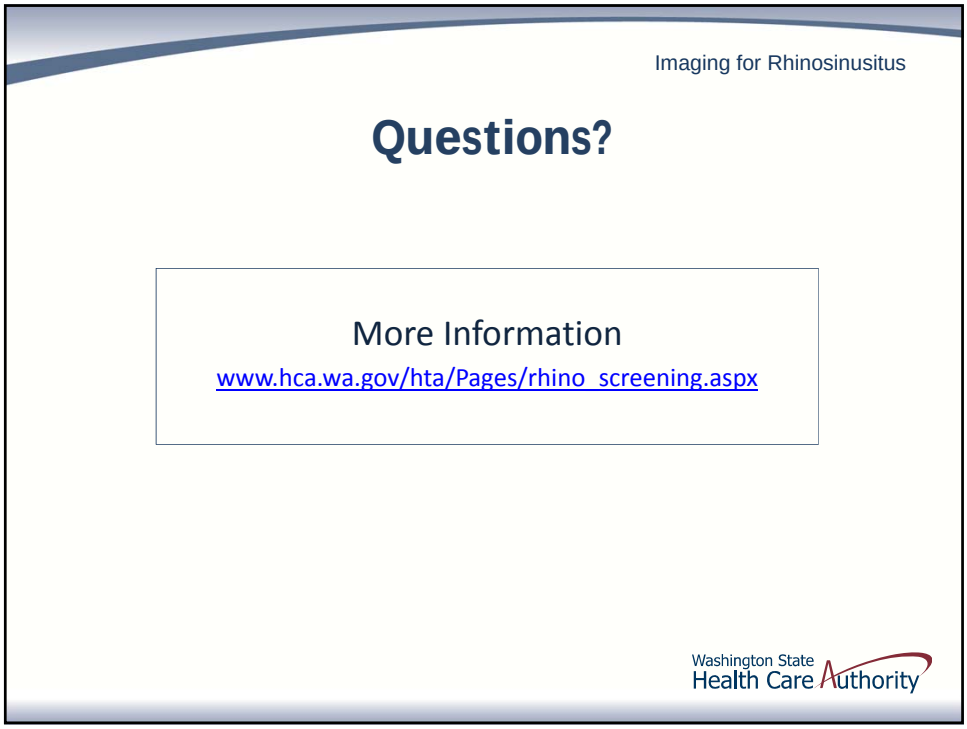
Washington State Health Care Authority


Imaging for Rhinosinusitus
Questions?
More Information
www.hca.wa.gov/hta/Pages/rhino_screening.aspx
Washington State
Health Care Authority

Washington State Health Care Authority
Health Technology Assessment

Order of Scheduled Presentations:

Imaging for Rhinosinusitus

	Name
1	
2	
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4	
5	
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No requests to provide public comment on the technology review were received.

Imaging for Rhinosinusitis

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Hayes, Inc.
May 15, 2015

Shorthand and abbreviations

- **Abx** – antibiotics
- **CRS** – chronic rhinosinusitis
- **CT** – computed tomography
- **Dx** – diagnosis
- **(F)ESS** – (functional) endoscopic sinus surgery
- **KQ** – Key question
- **MRI** – magnetic resonance imaging
- **NPV** – negative predictive value
- **PPV** – positive predictive value
- **RCT(s)** – randomized controlled trial(s)
- **RS** – rhinosinusitis
- **Sx** – symptom(s)
- **Tx** – treatment/treat
- **URI** – upper respiratory tract infections
- **US** – ultrasound

Presentation overview

- Background
- Scope, Methods, and Search Results
- Findings
- Practice Guidelines and Payer Policies
- Overall Summary and Discussion

Background

Rhinosinusitis

- Inflammation, lining of paranasal sinuses
  - Not necessarily due to infection
- Prevalence of CRS in Americans: 35 million
- Sx-based presumptive dx, acute bacterial RS
  - URI sx >10 days
  - Sx worsen after initial improvement
  - Severe sx or high fever
  - Nasal congestion, purulent rhinorrhea, facial-dental pain, postnasal drainage, headache, cough
- Predisposing factors
  - Allergies, cystic fibrosis, immunosuppression
  - Anatomic abnormalities
  - Recent dental work, trauma

Classification of RS

- Duration
  - Acute: <4 weeks
  - Subacute: 4-8 weeks
  - Chronic: >8 weeks; >12 weeks
- Recurrent
  - ≥3 episodes, asymptomatic between
- Reason for symptoms
  - Viral URI (etiology of ≥90% cases of RS)
    - Spontaneous cure rate, 98%
    - ≤2% (adults)/6%-7% (children) cases→ bacterial RS
  - Bacterial (2%-10% cases)
  - Fungal (invasive and noninvasive)
  - Allergic

Non-symptomatic confirmation of RS

- Aspiration-culture or histopathology — gold standard
- CT or nasal endoscopy: consider when Abx not effective
- CT and CRS
  - 20%-36% patients with sx have CT-confirmed disease
  - Lack of correlation between sx and CT findings
- MRI
  - Considered useful for suspected fungal RS or complications
- X-ray and US have also been investigated

Interpreting sinus imaging

- Radiographic staging, e.g., Lund Mackay
  - Each sinus scored 0-2 for opacity
  - Total score 0-24
  - 4 = typical cutoff value for dx of RS
  - Primarily used in research
- Otherwise, consider features, e.g.,
  - Mucosal thickening
  - Opacification
  - Presence of air-fluid level

Treatment of RS

- Abx: Sx >10 days, severe sx
  - Modestly effective , acute RS (3 systematic reviews)
    - 80% adults on placebo : improved at ≤ 2 weeks (1 review)
  - ↑Adverse events,
    - RR, 1.85 (CI, 1.21–2.90) (12 RCTs) (acute RS)
  - No comprehensive systematic review, CRS
- Adjunctive steroids
  - Intranasal: acute RS, CRS with polyps, allergic RS
  - Oral
  - Small body, positive evidence
- Immunotherapy for CRS, acute fungal RS
  - Some evidence of improvement (1 systematic review)
- Decongestants, antihistamines, nasal irrigation
  - No RCTs or quasi-RCTs

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Treatment of RS (cont.)

- Surgery
  - FESS
  - Purpose
    - Remove infected mucosal material
    - Correct complication (e.g., abscess, polyps)
  - Immunosuppressed patients, greater risk of invasive infection
  - 4 systematic reviews
    - No clear advantage of ESS over medical tx, adults/children with CRS
  - Imaging
    - Considered mandatory for surgical planning

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Policy Context

- Substantial utilization, WA HCA plans
- Imaging insufficiently accurate as gold standard
- Choosing Wisely (AAAAI)
  - Don't order sinus CT or indiscriminately prescribe antibiotics for uncomplicated acute rhinosinusitis. (#2 on list)
- Evidence-based assessment needed
  - Accuracy for confirming/refining dx of RS
  - Impact on outcomes and cost

AAAAI – American Academy of Allergy, Asthma & Immunology

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Scope, Methods, and Search Results

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PICO

- **Population:** Adults and children diagnosed with or suspected of having chronic, acute, or recurrent RS
- **Interventions:** CT, MRI, x-ray, US
- **Comparisons:** Clinical dx without imaging; another imaging modality
- **Outcomes:** Diagnostic performance (**accuracy**) in terms of sensitivity/specificity, positive predictive value (PPV)/negative predictive value (NPV), and positive/negative likelihood ratios; change in clinical **management decisions or utilization**; health **outcomes**; prevention of disease-related complications; **adverse events** associated with imaging (e.g., radiation exposure); **cost and cost-effectiveness**

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Key Questions

1. What is the **clinical performance (accuracy)** of imaging technologies such as CT, MRI, x-ray, and US for evaluation of RS or related complications?

1a. Does the clinical performance **vary by imaging modality** or technique?

2. What is the **clinical utility** of imaging for RS? What is the impact:

2a. On clinical management decisions and utilization?

2b. On health outcomes?

2c. According to different imaging modalities?

3. What are the **safety issues** associated with different forms of imaging technologies?

4. Does the diagnostic performance, impact on clinical management, impact on health outcomes, or incidence of adverse events **vary by clinical history or patient characteristics** (e.g., comorbidities, subtypes of RS)?

5. What are the **costs and cost-effectiveness** of imaging modalities in the diagnosis of sinusitis, including comparative costs and incremental cost-effectiveness when comparing modalities?

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Search Strategy

- Primary studies
  - No time limit
  - PubMed: October 24, 2014
  - Embase: November 7, 2014
  - Exclusion criteria for all KQs
    - Inpatient settings (e.g., ventilator-induced sinusitis)
    - Non-English-language publication
- Final update searches
  - March 20, 2015

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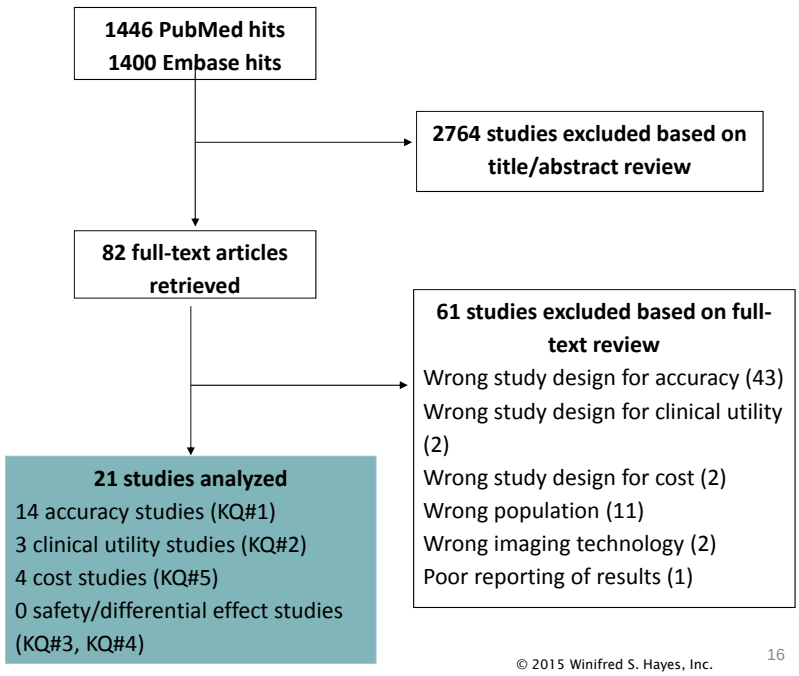

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Quality assessment aligns with GRADE system (Appendix II)

- Individual **study** appraisal
  - *Are the findings **valid**?*
    - Study design, execution, and analysis (checklist)
    - Internal validity (minimization of bias)
    - *Good–Fair–Poor–Very Poor*
- Evaluation of **body of evidence** for each outcome
  - *How **confident** are we that this evidence answers the Key Question?*
    - Domains:
      - –Study design and weaknesses
      - –Quantity/precision of data
      - –Publication bias
      - –Applicability to PICO
      - –Consistency, study findings
    - *High–Moderate–Low–Very Low*

Findings

(See Summary of Findings Tables and Appendix IV for further detail)

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Clinical interpretation of sensitivity

- Highly sensitive test
  - Maximize true-positives
  - Minimize false-negatives
  - (Sensitivity does not prevent false-positives)
- Clinical scenario
  - Pt has symptoms of disease
  - 100% sensitivity, 65% specificity
- Confidence in test results
  - Positive test: Low
  - Negative test: High

SnNout
High **Sen**sitivity,
Negative test, rule **out**

Clinical interpretation of specificity

- Highly specific test
  - Maximize true-negatives
  - Minimize false-positives
  - (Specificity does not prevent missed cases)
- Clinical scenario
  - Pt has symptoms of disease
  - 60% sensitivity, 95% specificity
- Confidence in test results
  - Positive test: High
  - Negative test: Low

SpPin
High **Sp**ecificity,
Positive test, rule **in**

KQ #1 Preview: Clinical performance by modality

- **CT**
  - **Dx of acute/chronic RS**
    - Unknown accuracy
    - Indirect evidence, CRS: Correlation studies
  - **Dx of fungal RS**
    - Variable sensitivity, good specificity
    - 6 studies, *low-quality evidence*
  - **Preoperative prognosis**
    - May predict adverse events (1 study; *low quality)*
    - Unknown: Health benefits

KQ #1 Preview: Clinical performance by modality (cont.)

- **X-ray** (CT as reference standard)
  - **Dx of acute RS**
    - Moderate sensitivity, variable specificity (3 studies; *low quality)*
  - **Dx of CRS**
    - Moderate overall accuracy, variable sensitivity, variable specificity (3 studies; *low quality)*
- **US** (CT as reference standard)
  - **Dx of CRS**
    - Low accuracy (1 study; *very low quality)*
- **MRI**
  - **Detection of fungal RS** *(*1 study; *very-low-quality evidence*)
    - High sensitivity and moderate specificity
    - Sensitivity superior to CT

Classification	Findings for KQ#1 and #1a	# Studies, Overall Quality
Acute RS	**Diagnosis: X-ray (against CT)** • Moderate to moderately high sensitivity & variable specificity	3, low
	• Diagnosis: CT, MRI, US • Variation in clinical performance by modality	0, insufficient evidence
Chronic RS (CRS)	**Prognosis: CT (against surgical adverse events)** • No obvious Lund-Mackay cutoff value	1, low
	Diagnosis: X-ray (against CT) • Moderate/mod high accuracy; variable sensitivity, variable specificity	3, low
	Diagnosis: US (against CT): Low accuracy	1, very low
	• Diagnosis: CT*, MRI • Prognosis: X-ray, MRI, US • Variation in clinical performance by modality	0, insufficient evidence

**Indirect evidence: Correlation between CT staging and histopathology, CRS*

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Classification	Findings for KQ#1 and #1a	# Studies, Overall Quality
Fungal RS	**Diagnosis: CT (against histopathology)** • Variable sensitivity, moderate to moderately high specificity	6, low
	Diagnosis: MRI (against histopathology) • High sensitivity & moderate specificity	1, very low
	Diagnosis: MRI vs. CT (against histopathology) • Sensitivity: MRI > CT • Specificity: MRI ≈ CT	1, very low
	• Diagnosis: x-ray, US	0, insufficient evidence

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Classification	Findings for KQ#1	# Studies, Overall Quality
Acute RS	**Diagnosis: X-ray (against CT)** • Moderate to moderately high sensitivity & variable specificity	3, low
	• Diagnosis: CT, MRI, US • Variation in clinical performance by modality	0, insufficient evidence

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KQ#1: Accuracy of x-ray, dx of acute RS

Evidence	Diagnostic Accuracy for Maxillary Sinuses
3 studies (n=119) Burke 1994 (n=30) Retrospective cohort (good) Chiu 2010 (n=42) Prospective cohort (fair) Aaløkken 2003 (n=47) Cross-sectional (fair) **Index test:** X-ray **Reference standard:** CT **Low overall quality** (few studies, small sample sizes, inconsistent specificity, imperfect reference standard)	Moderate-moderately high sensitivity: 70%-89% Variable specificity: 43%-100% Variable PPV: 14%-90% Variable NPV: 43%-89%

Classification	Findings for KQ#1 and #1a	# Studies, Overall Quality
Chronic RS (CRS)	**Prognosis: CT (against surgical findings)** • No obvious Lund-Mackay cutoff value	1, low
	Diagnosis: X-ray (against CT) • Moderate/mod high accuracy; variable sensitivity, variable specificity	3, low
	Diagnosis: US (against CT): Low accuracy	1, very low
	• Diagnosis: CT*, MRI • Prognosis: X-ray, MRI, US • Variation in clinical performance by modality	0, insufficient evidence

**Indirect evidence: Correlation between CT staging and histopathology*

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KQ#1: Accuracy of preoperative CT for prognosis of adverse events, CRS

Evidence	Predictive Relationship
Hopkins 2007 (n=1840) Prospective cohort (fair) **Index test:** CT **Reference standard:** Surgical confirmation **Low overall quality** (single study, incomplete control)	**Adjusted OR for 1-point increase in Lund-Mackey score (95% CI):** Complication: **1.09 (1.06-1.13), *P*=0.001** Revision surgery within 12 mos: 1.006 (0.96-1.05), NS Revision surgery within 36 mos: **1.03 (1.001-1.06), *P*=0.046** No evidence for cutoff score score 21%, score 0-4

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KQ#1: Accuracy of x-ray, dx of CRS

Evidence	Diagnostic Accuracy for Maxillary Sinuses
3 studies (n=217) Konen 2000 (n=134) Cross-sectional (good) Timmenga 2002 (n=40) Cross-sectional (good) Kasapoğlu 2009 (n=43) Prospective cohort (fair) **Index test:** X-ray **Reference standard:** CT **Low overall quality** (few studies, small sample sizes, inconsistency, imperfect reference standard)	Moderate-moderately high overall accuracy: 77%-87% Variable sensitivity: 68%-95% Variable specificity: 53%-88% Moderate-high PPV: 73%-95% Moderate-high NPV: 73%-89%

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KQ#1: Accuracy of US, dx of CRS

Evidence	Diagnostic Accuracy
Vento 1999 (n=40) Retrospective cohort (good) **Index test:** US **Reference standard:** CT **Very low overall quality** (very sparse data)	Low overall accuracy: 44%-68% Low sensitivity: 28%-50% Variable specificity: 48%-81% Low PPV: 23%-58% Low-moderate NPV: 44%-77% *Reflects results for 2 observers and 2 CT features.*

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Classification	Findings for KQ#1 and #1a	# Studies, Overall Quality
Fungal RS	**Diagnosis: CT (against histopathology)** • Variable sensitivity, moderate to moderately high specificity	6, low
	Diagnosis: MRI (against histopathology) • High sensitivity & moderate specificity	1, very low
	Diagnosis: MRI vs. CT (against histopathology) • Sensitivity: MRI > CT • Specificity: MRI ≈ CT	1, very low
	• Diagnosis: x-ray, US	0, insufficient evidence

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KQ#1: Accuracy of CT, dx of fungal RS

Evidence	Diagnostic Accuracy
6 studies (n=1244) 3 cohort (fair) 2 case-control (1 poor, 1 fair) 1 cross-sectional (fair) **Index test:** CT **Reference standard:** Histopathology **Low overall quality** (few studies per indication, small sample sizes, inconsistent sensitivity)	Variable sensitivity: 36%-93% Moderately high-high specificity: 83%-100% Variable PPV: 56%-93% (*due to differences in prevalence*) Variable NPV: 4 40%-98%

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KQ#1: Accuracy of CT, dx of fungal RS (4 cohort/cross-sectional studies)

High Prevalence, High PPV	Low Prevalence, Low PPV
Lenglinger 1996 (n=21; fair) **(dx of maxillary sinus aspergillosis, following screening by x-ray, recent endodontic work)** Sensitivity: 93.3% Specificity: 83.3% **PPV: 93.3% (prevalence 71%)** **NPV: 83.3%** **Groppo 2011 (n=23; fair)** **(dx of invasive fungal RS, immunocompromised pts)** Sensitivity: 69%, 57% Specificity: 83%, 83% **PPV: 92%, 91% (prevalence 74%)** **NPV: 48%, 40%**	**Yoon 1999 (n=510; fair)** **(dx of fungal RS)** Sensitivity: 51.3% Specificity: 96.6% **PPV: 55.6%* (prevalence 8%)** **NPV: 96%** **Broglie 2009 (dx of sinus fungal ball) (n=615; fair)** Sensitivity: 83% Specificity: 94% **PPV: 56%* (prevalence 9%)** **NPV: 98%**

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KQ#1 and #1a: Accuracy of MRI vs CT, dx of fungal RS

Evidence	Diagnostic Accuracy by Imaging Modality
Groppo 2011 (n=23) Retrospective cohort study (fair) **Index test:** CT and MRI **Reference standard:** Histopathology **Very low overall quality** (very sparse data)	**Invasive fungal RS, immunocompromised pts** **MRI** : Sensitivity: 85%–86% Specificity: 75% PPV: 90%–91% NPV: 64%–65% **CT**: Sensitivity: 57%–69% Specificity: 83% PPV: 91%–92% NPV: 40%–48% *Reflects results for 2 observers.*

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Indirect evidence: Accuracy of CT for dx of CRS

- Positive correlation (2 studies)
  - CT scores vs culture rate (1 study)
  - CT scores vs severity by inflammatory markers (1 study)
    - Correlation between sx and pathology score NS
- Suggests relationship between CT results and infection/inflammation
  - But sensitivity and specificity unknown

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KQ #1 Recap: Clinical performance by modality

- CT
  - **Dx of acute/chronic RS**
    - Unknown accuracy
    - Indirect evidence, CRS: Correlation studies
  - **Dx of fungal RS** (histopathology as reference standard)
    - Variable sensitivity, good specificity
    - 6 studies, *low-quality evidence*
  - **Preoperative prognosis**
    - May predict adverse events (1 study; *low quality)*
    - Unknown: Health benefits

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KQ #1 Recap: Clinical performance by modality (cont)

- **X-ray** (CT as reference standard)
  - **Dx of acute RS**
    - Moderate sensitivity, variable specificity (3 studies; *low quality)*
  - **Dx of CRS**
    - Moderate overall accuracy, variable sensitivity, variable specificity (3 studies; *low quality)*
- **US** (CT as reference standard)
  - **Dx of CRS**
    - Low accuracy (1 study; *very low quality)*
- **MRI** (histopathology as reference standard)
  - **Detection of fungal RS** *(*1 study; *very-low-quality evidence*)
    - High sensitivity and moderate specificity
    - Sensitivity superior to CT

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KQ#2: Clinical utility of imaging

Indication	Findings for KQ #2	# Studies, Overall Quality
Acute RS*	All subquestions	0, insufficient evidence
Chronic RS	**Clinical management decisions and utilization (2a): CT** • May alter decisions regarding surgery • uCT may reduce use of Abx in pts with negative endoscopy	3, very low
	• 2a: Modalities other than CT • 2b: Impact on health outcomes • 2c: Differential impact by imaging modality	0, insufficient evidence
Fungal RS	All subquestions	0, insufficient evidence

**Indirect evidence: Use of imaging does not improve Abx effectiveness*

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KQ #2a: Impact of CT on decisions and utilization, CRS

Evidence	Results
3 studies (n=157) Anzai 2004 Pretest/posttest (very poor) Conley 2011 Observational with historical controls (very poor) Tan 2011 Single-blind RCT (fair) **Very low overall quality** (2 of 3 studies very poor)	**Anzai 2004 (n=27)** Change in surgeons' opinion, appropriateness of surgery: 26%-37% cases (3 surgeons) **Conley 2011 (n=90)** % patients with medical tx at 1st visit, uCT vs EMT: Abx: 35% vs 37.5% (NS) Abx after negative endoscopy: 0 vs 12%* Oral steroid: 35% vs 5% (*P*=0.0021) **Tan 2011 (n=40)** % pts upfront CT vs EMT*: Abx: 40% vs100% Nasal steroid: 80% vs 75% Oral steroid: 30% vs 35% **P* unknown

KQ #2a: Indirect evidence, impact on outcomes, acute RS

- 2 meta-analyses, RCTs of Abx
  - Adults or children, 17 RCTs (Falagas 2008):
    - Small and nonsignificant difference: Imaging vs no imaging
  - Adults, 9 RCTs (Cochrane Review, Ahuvuo-Saloranta 2014)
    - No difference: Clinical dx alone vs radiological/bacteriological confirmation
- (No indirect evidence, CRS)

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KQ #3: Safety

- No direct assessment in eligible studies
- Minimal risks, occasional use: CT, MRI, x-ray, US
  - But possible concern, frequent use: CT and x-ray

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KQ #4: Differential performance or impact according to clinical history, patient characteristics?

- 8 of the 14 studies analyzed for KQ #1
  - Children and adolescents as well as adults
  - Results not reported separately for children and adults
- No within-study results by other patient characteristics
- No obvious variation across studies (other than by type of RS)

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KQ #5: Cost Implications

	Findings for KQ#5	Source/Comments
Cost, CT sinus	$272 for CT sinus scan in 2010	Medicare
Cost comparison, upfront CT (uCT) vs empiric medical tx for chronic RS	Save overall costs Or At minimum, reduce medication costs In patients with negative or no endoscopy	4 studies 3 modelling; 1 trial-based -Same institution -uCT not recommended by specialty societies
Other possible cost comparisons: Acute RS Fungal RS X-ray, MRI, or US vs no imaging		No studies
Cost-effectiveness		No studies

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KQ #5: Cost comparison, upfront CT (uCT) vs empiric medical tx (EMT) for chronic RS

- 4 cost comparisons
  - 3 modelling, 1 RCT
  - 3 tertiary care, 1 primary care
- Limitations
  - Modelling
    - Non-medication costs from Medicare rates
    - Tx response rates not based on systematic reviews
  - Trial-based
    - Total costs not computed
  - All
    - No outcomes data
    - Same institution
    - Routine uCT not recommended by guidelines

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KQ #5: Cost comparison, uCT vs EMT for chronic RS (cont.)

Per Patient with Negative Endoscopy	
Leung 2011 **Modelling** **Tertiary care**	**Mean overall cost savings with uCT** Same-day CT available: $321 Same-day CT not available: $297 Median assumptions for CRS medication costs, rates of AEs, and medical tx response rates.
Tan 2011 **RCT** **Tertiary care**	**Mean medication costs) (uCT vs EMT)** All: $218 vs $253 (NS) Abx: $53 vs $153 ($P<0.05$)

Note: Costs are for 2010

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KQ #5: uCT vs EMT for chronic RS (cont.)

Per Patient	
Tan 2013 **Modelling, tertiary care**	**Overall savings with uCT** Same-day CT available: $186 With positive endoscopy: -$133 Same-day CT not available: $20 With positive endoscopy: -$288 *Median cost and tx response assumptions using sx set recommended by AAO-HNS. Lower and higher estimates with other sx sets.*
Leung 2014 **Modelling, primary care setting**	**Overall savings with uCT in primary care office*** PCP treats CRS: >$503 PCP refers for tx of CRS: $326 **vs EMT for positive endoscopy after otolaryngology referral .*

Note: Costs are for 2010

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Practice Guidelines and Payer Policies

Aetna Policy

- Paranasal sinus US
  - Experimental and investigational
- No other policies regarding imaging and RS

6 Practice Guidelines	
Classification of RS (2 GLs, fair)	• Acute RS: Lasting <4 weeks • Subacute RS: Lasting 4–8 weeks • CRS: Mixed (>8 weeks; or >12 weeks)
Clinical Dx of Acute Bacterial RS (6 GLs, 3 good, 3 fair)	• URI sx lasting >10 days – sx that worsen after initial improvement – severe sx or high fever • Nasal congestion – purulent rhinorrhea – facial or dental pain – postnasal drainage – headache – cough
Imaging (6 GLs, 3 good, 3 fair)	Imaging: Cannot decide bacterial vs viral CT: Complications suspected and/or sx do not improve MRI: Complementary to or alternative to CT, special situations US: Pregnant women, determining amounts of retained sinus secretions X-ray: CT is preferred
Repeated Imaging (1GL, good)	• CT findings provide an objective method for monitoring

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Overall Summary and Discussion

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Summary of findings and guidelines: CT

- **Dx of acute/chronic RS**
  - Unknown accuracy
  - Positive correlation, CT scans for CRS and postop histopathology (2 studies)*
- **Dx of fungal RS**
  - Variable sensitivity, good specificity
  - 6 studies, *low-quality evidence*
- **Preoperative prognosis:**
  - May predict adverse events
    - 1 study; *low quality)*
  - Unknown: Health benefits
- **Clinical utility**
  - May change decisions for surgery or reduce Abx
    - 3 studies; *low quality*
  - No association, imaging and effect of Abx for acute RS (2 meta-analyses)*
- **Cost implications**
  - uCT may save overall/meds costs
    - 4 studies at same institution, serious limitations
- **Guidelines**
  - Evaluate complications, no response to Abx for CRS
  - Suspected tumor
  - Preoperative planning

*Indirect evidence

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Summary of findings and guidelines: X-ray, US, MRI

- **X-ray** (CT as reference standard)
  - Moderate sensitivity, variable specificity for **acute RS** (3 studies; *low quality)*
  - Moderate overall accuracy, low specificity for **chronic RS** (3 studies; *low quality)*
- **Ultrasound** (CT as reference standard)
  - Low accuracy for **chronic RS** (1 study; *very low quality)*
- **MRI**
  - Detection of **fungal RS** *(*1 study; *very-low-quality evidence*)
    - High sensitivity and moderate specificity
    - Sensitivity superior to CT
  - Unknown accuracy for other indications
- **Unknown clinical utility**
- **Routine use not supported by guidelines**

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Additional research needed for all Key Questions

- Large observational studies
  - Accuracy of imaging for dx
  - Prognosis of surgical outcomes
- RCTs
  - Clinical management decisions, utilization
  - Health outcomes
  - Costs
- CT vs (x-ray), MRI, (US)
- Differential accuracy and clinical utility, e.g., by
  - # previous episodes
  - Duration of sx
  - Risk factors for complications

Thank you!

QUESTIONS?

HTCC Coverage and Reimbursement Determination Analytic Tool

HTA's goal is to achieve *better health care outcomes* for enrollees and beneficiaries of state programs by paying for proven health *technologies that work*.

To find best outcomes and value for the state and the patient, the HTA program focuses on three questions:

1. Is it safe?
2. Is it effective?
3. Does it provide value (improve health outcome)?

The principles HTCC uses to review evidence and make determinations are:

Principle One: Determinations are evidence-based

HTCC requires scientific evidence that a health technology is safe, effective and cost-effective[1] as expressed by the following standards[2]:

- Persons will experience better health outcomes than if the health technology was not covered and that the benefits outweigh the harms.
- The HTCC emphasizes evidence that directly links the technology with health outcomes. Indirect evidence may be sufficient if it supports the principal links in the analytic framework.
- Although the HTCC acknowledges that subjective judgments do enter into the evaluation of evidence and the weighing of benefits and harms, its recommendations are not based largely on opinion.
- The HTCC is explicit about the scientific evidence relied upon for its determinations.

Principle Two: Determinations result in health benefit

The outcomes critical to HTCC in making coverage and reimbursement determinations are health benefits and harms[3]:

- In considering potential benefits, the HTCC focuses on absolute reductions in the risk of outcomes that people can feel or care about.
- In considering potential harms, the HTCC examines harms of all types, including physical, psychological, and non-medical harms that may occur sooner or later as a result of the use of the technology.
- Where possible, the HTCC considers the feasibility of future widespread implementation of the technology in making recommendations.
- The HTCC generally takes a population perspective in weighing the magnitude of benefits against the magnitude of harms. In some situations, it may make a determination for a technology with a large potential benefit for a small proportion of the population.
- In assessing net benefits, the HTCC subjectively estimates the indicated population's value for each benefit and harm. When the HTCC judges that the balance of benefits and harms is likely to vary substantially within the population, coverage or reimbursement determinations may be more selective based on the variation.
- The HTCC considers the economic costs of the health technology in making determinations, but costs are the lowest priority.

[1] Based on Legislative mandate: See RCW 70.14.100(2).

[2] The principles and standards are based on USPSTF Principles at: http://www.ahrq.gov/clinic/ajpmsuppl/harris3.htm

[3] The principles and standards are based on USPSTF Principles at: http://www.ahrq.gov/clinic/ajpmsuppl/harris3.htm

Using evidence as the basis for a coverage decision

Arrive at the coverage decision by identifying for Safety, Effectiveness, and Cost whether (1) evidence is available, (2) the confidence in the evidence, and (3) applicability to decision.

1. Availability of Evidence:

Committee members identify the factors, often referred to as outcomes of interest, that are at issue around safety, effectiveness, and cost. Those deemed key factors are ones that impact the question of whether the particular technology improves health outcomes. Committee members then identify whether and what evidence is available related to each of the key factors.

2. Sufficiency of the Evidence:

Committee members discuss and assess the evidence available and its relevance to the key factors by discussion of the type, quality, and relevance of the evidence[4] using characteristics such as:

- Type of evidence as reported in the technology assessment or other evidence presented to committee (randomized trials, observational studies, case series, expert opinion);
- The amount of evidence (sparse to many number of evidence or events or individuals studied);
- Consistency of evidence (results vary or largely similar);
- Recency (timeliness of information);
- Directness of evidence (link between technology and outcome);
- Relevance of evidence (applicability to agency program and clients);
- Bias (likelihood of conflict of interest or lack of safeguards).

Sufficiency or insufficiency of the evidence is a judgment of each clinical committee member and correlates closely to the GRADE confidence decision.

Not Confident	Confident
Appreciable uncertainty exists. Further information is needed or further information is likely to change confidence.	Very certain of evidentiary support. Further information is unlikely to change confidence

3. Factors for Consideration - Importance

At the end of discussion a vote is taken on whether sufficient evidence exists regarding the technology's safety, effectiveness, and cost. The committee must weigh the degree of importance that each particular key factor and the evidence that supports it has to the policy

[4] Based on GRADE recommendation: http://www.gradeworkinggroup.org/FAQ/index.htm

and coverage decision. Valuing the level of importance is factor or outcome specific but most often include, for areas of safety, effectiveness, and cost:

- Risk of event occurring;
- The degree of harm associated with risk;
- The number of risks; the burden of the condition;
- Burden untreated or treated with alternatives;
- The importance of the outcome (e.g. treatment prevents death vs. relief of symptom);
- The degree of effect (e.g. relief of all, none, or some symptom, duration, etc.);
- Value variation based on patient preference.

HEALTH TECHNOLOGY EVIDENCE IDENTIFICATION

Discussion Document:

What are the key factors and health outcomes and what evidence is there?

Outcomes	Evidence
Safety	**Safety**
Radiation exposure	
Missed/delayed diagnosis	
Efficacy – Effectiveness	**Efficacy / Effectiveness**
Sensitivity/specificity	
PPV/NPV	
Clinical management decisions	
Improved health outcomes	
Special Population / Considerations	**Special Populations/ Considerations**
Age	
Comorbidities	

Cost	Cost
Cost	
Cost-effectiveness	

Medicare Coverage and Guidelines

[From Final Evidence Report page 68]

Centers for Medicare & Medicaid Services (CMS)

No CMS National Coverage Determination (NCD) was identified for imaging for RS on January 7, 2015 (search National Coverage Documents in National Coverage Determinations and Medicare Coverage Documents at: CMS Advanced Search Database). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

[From Final Evidence Report Appendix V page 99]

APPENDIX V. Summary of Practice Guidelines

Key: α, alpha; ABRS, acute bacterial rhinosinusitis; Abx, antibiotics; AR, allergic rhinitis; btwn, between; CT, computed tomography; dx, diagnosis; hx, history; IVIG, intravenous immunoglobulin; MRI, magnetic resonance imaging; pt(s), patient(s); RS, rhinosinusitis; sx, symptoms; tx, treatment/therapy; URI, upper respiratory tract infection; US, ultrasound; VRS, viral rhinosinusitis

Sponsor, Title	Relevant Recommendations			Quality/Main Limitations
	Diagnosis	Treatment	Repeat Testing	
American Academy of Allergy, Asthma, and Immunology (AAAAI); American College of Allergy, Asthma & Immunology (ACAAI) (Slavin et al., 2005) *The Diagnosis and Management of Sinusitis: A Practice Parameter Update*	***Classification of RS:*** Acute: Sx lasting <4 wks; sx may include persistent sx of URI, purulent rhinorrhea, postnasal drainage, anosmia, nasal congestion, facial pain, headache, fever, cough, and purulent discharge Subacute: Sx lasting 4-8 wks Chronic RS: Sx lasting ≥8 wks; there should be abnormal CT or MRI findings Recurrent RS: ≥3 episodes of acute RS per yr ***Presumed ABRS:*** ABRS is suspected in pts w/ URI lasting >10-14 days. A hx of persistent purulent rhinorrhea, postnasal drainage, and facial pain correlates w/ increased likelihood of ABRS. (Grade A recommendation) Prominent sx of ABRS include nasal congestion, purulent rhinorrhea, facial-dental pain, postnasal drainage, headache, and cough. (Grade C recommendation) ***Imaging:*** To confirm dx when sx are vague, physical findings are equivocal, or clinical disease persists despite optimal medical tx. (Grade B recommendation) *US:* Limited utility but might be useful in pregnant women or for determining amounts of retained sinus secretions. (Grade C recommendation) (Not mentioned in algorithm) *Standard radiographs:* Might be used to detect acute ABRS; not sensitive, particularly for ethmoid disease. (Grade C recommendation) (Not mentioned in algorithm)	***Abx:*** Primary tx for bacterial RS. (Grade A recommendation). Inappropriate and discouraged strongly for uncomplicated viral URI. (Grade D recommendation) Duration not well defined. (Grade D recommendation) Concern has been raised about the overdiagnosis of RS and unnecessary tx w/ Abx. Appropriate criteria for the use of Abx are sx of RS for 10-14 days or severe sx of acute sinus infection, including fever w/ purulent nasal discharge, facial pain or tenderness, and periorbital swelling. Extended Abx tx or a different Abx to be considered if initial trial is unsuccessful. (Not formal recommendations) ***Antihistamines:*** No data to recommend the use of H_1 antihistamines in acute bacterial RS. (Grade D recommendation) Possible role for antihistamines in chronic RS if the underlying risk factor is AR. (Grade D recommendation) ***α-Adrenergic decongestants:*** Topical and oral decongestants are often used in the tx of acute or chronic RS because they decrease nasal resistance and theoretically increase ostial patency. (Grade D recommendation) Prospective studies are lacking and are needed to assess the value of α-adrenergic agents in the prevention or tx of RS. (Grade D recommendation) ***Glucocorticosteroids:*** The use of systemic corticosteroid tx for sinus disease has not been studied systematically in a well-controlled or blinded manner.	No recommendations	4.5—Fair (criteria for selecting evidence not described, methods for formulating recommendations not described, guideline review and update process not described)

Sponsor, Title	Relevant Recommendations			Quality/Main Limitations
	Diagnosis	Treatment	Repeat Testing	
	CT:[5,6] Optimal technique for evaluating ethmoid sinuses and for preoperative evaluation of nose and paranasal sinuses, including assessment of the ostiomeatal complex areas. (Grade C recommendation) NOTE: Algorithm advises to *consider* CT and/or nasal endoscopy if Abx tx is not successful; no distinction btwn acute and chronic RS. *MRI:*[7] Sensitive technique for evaluating suspected fungal RS and for differentiating btwn inflammatory disease and malignant tumors. Limited in its ability to define bony anatomy. (Grade C recommendation) (Not mentioned in algorithm)	(Grade D recommendation) A few recent studies suggest that the addition of intranasal corticosteroids as an adjunct to Abx tx might be modestly beneficial in the tx of pts w/ recurrent acute or chronic RS. (Grade C recommendation) ***Adjunctive tx:*** *Saline, mucolytics, and expectorants:* There are several scientific studies that imply but do not directly confirm a role for these agents in RS. (Grade D recommendation) Use of all these agents as prophylaxis for exacerbations of chronic RS is empiric and not supported by clinical data. (Grade D recommendation) These agents are commonly used and in some instances might be beneficial in some pts. (Grade D recommendation) ***IVIG:*** Immunodeficiency might be an underlying risk factor for the development of recurrent acute or chronic RS. (Grade B recommendation) IVIG is approved as a replacement tx for antibody deficiency disorders (e.g., X-linked agammaglobulinemia, common variable immunodeficiency). (Grade A recommendation) Appropriate use of IVIG can prevent complications from chronic RS, including subperiosteal and intracranial abscesses, meningitis, sepsis, and death. (Grade B recommendation) ***Aspirin-desensitization tx****:* Beneficial effects of aspirin desensitization on pts w/ aspirin-exacerbated respiratory disease (AERD) have been reported. (Grade		

[5]Indications for CT: recurrent acute sinusitis, chronic sinusitis, preoperative evaluation prior to sinus surgery, nasal polyposis, persistent and nasal congestion-obstruction, immunocompromised pt w/ fever, dentomaxillary pain, facial pressure-headache unresponsive to medical tx.
[6]Indications for CT w/ contrast: complications of sinusitis (periorbital edema, subperiosteal abscess), sinonasal tumor.
[7]Indications for MRI w/ contrast: skull base dehiscence with opacification, unilateral sinonasal opacification (on CT), sinonasal process with cranial extension, expansile sinonasal mass with bony erosion, sinonasal mass with orbital extension, biopsy-proven tumor, fungal sinusitis.

Sponsor, Title	Relevant Recommendations			Quality/Main Limitations
	Diagnosis	Treatment	Repeat Testing	
		A recommendation) ***Surgery:*** Antral puncture and irrigation is an office procedure that has a place in the management of acute ethmomaxillary RS refractory to medical tx, or in acute RS in an immunosuppressed pt in which early identification of pathogenic organisms is paramount. (Grade D recommendation) Surgical intervention might be required in acute RS to provide drainage when there is a significant risk of intracranial complication or in a pt w/ periorbital or intraorbital abscess or visual compromise. (Grade D recommendation) Functional endoscopic sinus surgery, in combination w/ appropriate medical tx, has been shown in uncontrolled studies to have long-term efficacy in reducing disease-specific sx and in improving overall quality of life. (Grade C recommendation)		
American Academy of Otolaryngology–Head and Neck Surgery Foundation (AAO-HNSF) (Rosenfeld et al., 2007) *Clinical Practice Guideline: Adult Sinusitis* The AAO-HNSF is scheduled to publish an update to the adult sinusitis guidelines in April 2015.	*Presumed ABRS:* Diagnose ABRS when (a) sx or signs of acute RS are present >10 days beyond the onset of upper respiratory sx, or (b) sx or signs of acute RS worsen w/in 10 days after an initial improvement (double worsening). *Strong recommendation* ***Endoscopy/Radiographic imaging:*** <u>Acute</u>: *Not* recommended unless a complication or alternative dx is suspected. *Recommendation against* <u>Chronic or recurrent acute</u>: Nasal endoscopy. *Option* CT of the paranasal sinuses. *Recommendation* (A dx of chronic RS requires documentation of inflammation by rhinoscopy, nasal endoscopy, or radiographic imaging.) Clinicians should distinguish chronic RS and recurrent acute RS from isolated episodes of ABRS and other causes of sinonasal sx. *Recommendation* Clinicians should assess the pt w/ chronic RS or recurrent acute RS for factors that modify management, such as AR, cystic fibrosis, immunocompromised state, ciliary dyskinesia, and anatomic variation. *Recommendation*	Symptomatic relief for managing VRS or ABRS. *Option* Analgesic tx for presumed ABRS based on severity of pain. *Strong recommendation* Observation w/o use of Abx for adults w/ uncomplicated ABRS who have mild illness (mild pain and temperature <38.3°C/101°F) and assurance of f/u. *Option* If a decision is made to treat ABRS w/ an Abx agent, the clinician should prescribe amoxicillin as first-line tx for most adults. If the pt worsens or fails to improve w/ the initial management option by 7 days after dx, the clinician should reassess the pt to confirm ABRS, exclude other causes of illness, and detect complications. If ABRS is confirmed in the pt initially managed w/ observation, the clinician should begin Abx tx. If the pt was initially managed w/ an Abx, the clinician should change the antibiotic. *Recommendation* ***Surgery:*** No recommendations on surgery are made in	No recommendations. (However, discussion states that CT findings provide an objective method for monitoring.)	6—Good (source of funding NR)

Sponsor, Title	Relevant Recommendations			Quality/Main Limitations
	Diagnosis	Treatment	Repeat Testing	
	The clinician should corroborate a dx and/or investigate for underlying causes of chronic RS and recurrent acute RS. *Recommendation* The clinician may obtain testing for allergy and immune function in evaluating a pt w/ chronic RS or recurrent acute RS. *Option based on observational studies w/ an unclear balance of benefit vs harm*	the guidelines.		
American Academy of Pediatrics (Smith et al., 2013; Wald et al., 2013) *Clinical Practice Guideline for the Diagnosis and Management of Acute Bacterial Sinusitis in Children Aged 1 to 18 Years*	***Presumed ABRS:*** Diagnose ABRS when child w/ URI presents w/ (a) persistent illness >10 days w/o improvement, (b) worsening course after initial improvement, (c) severe onset (temperature ≥39°C/102.2°F) and purulent nasal discharge for ≥3 days. *Recommendation* Reassessment: If caregiver reports worsening (progression of initial sx or appearance of new sx) *or* failure to improve (lack of reduction in all presenting sx) w/in 72 hrs of initial management. *Recommendation* ***Radiographic imaging:*** Dx: *Not* recommended to distinguish ABRS from viral URI. *Strong recommendation against* Suspected complications: Clinicians should obtain a contrast-enhanced CT scan of the paranasal sinuses and/or an MRI w/ contrast if a child is suspected of having orbital or central nervous system complications of ABRS. *Strong recommendation* Recurrent ABRS: Contrast-enhanced CT, MRI, or endoscopy, or all 3 should be performed for detection of obstructive conditions, particularly in children w/ craniofacial abnormalities. (Not a formal, graded recommendation)	***Severe onset and worsening course ABRS:*** Abx for acute ABRS w/ severe or worsening sx. *Strong recommendation* Persistent illness: Abx or additional observation for 3 days for persistent illness (nasal discharge and/or cough for ≥10 days w/o improvement). *Strong recommendation* First-line: Amoxicillin w/ or w/o clavulanate. *Recommendation* Reassessment: If the dx of ABRS is confirmed in a child w/ worsening sx or failure to improve in 72 hrs, consider changing Abx for the child initially managed w/ Abx or initiate Abx tx of the child initially managed w/ observation. *Option* Adjuvant tx: No recommendation for ABRS, including intranasal corticosteroids, saline nasal irrigation or lavage, topical or oral decongestants, mucolytics, and topical or oral antihistamines. *No recommendation* *Recurrent ABRS:* ABRS episodes lasting <30 days and separated by intervals of ≥10 days. Some experts require ≥4 episodes/yr to diagnose. Pt should be evaluated for underlying allergies, quantitative and functional immunologic defect(s), dysmotile cilia syndrome, and anatomic abnormalities. *No recommendation*	No recommendations	6.5—Good (methods for formulating consensus recommendations not described, procedure for update of guideline NR)
American College of Radiology (ACR) (ACR, 2012a; ACR, 2012b) *ACR Appropriateness Criteria: Sinusitis (Child and Adult)*	Gold standard for dx of ABRS is recovery of high-density bacteria ($\geq 10^4$ colony-forming units/mL) from sinus aspirate. However, this method is not feasible for the primary care practitioner and is invasive, time-consuming, and potentially painful. ***ABRS:*** Bacterial RS that lasts <30 days and whose sx resolve completely. A common sx of ABRS is URI w/ purulent nasal drainage. Severe ABRS is associated w/	The differentiation btwn viral and bacterial RS and the decision about whether to treat w/ Abx may be difficult. Adjuvant tx may include saline nasal irrigation, antihistamines, decongestants, mucolytic agents, and topical intranasal steroids.	No recommendations	4—Fair (systematic search methods and criteria for selecting evidence not described, methods for formulating recommendations not described, guideline not reviewed by external

Sponsor, Title	Relevant Recommendations			Quality/Main Limitations
	Diagnosis	Treatment	Repeat Testing	
	high fever and headache that is typically above or behind the eyes. ***Subacute RS:*** Sx lasting 4-12 wks (28-84 days) ***Recurrent ABRS:*** Episodes lasting <30 days each and separated by intervals of ≥10 asymptomatic days. ***Chronic RS:*** Lasts >90 days and pts have persistent residual respiratory sx (cough, rhinorrhea, or nasal obstruction) ***Imaging:*** Routine imaging of the paranasal sinuses in children and adults w/ ABRS w/o complications is not recommended. It is not useful for differentiating btwn viral and bacterial RS and usually does not change management in uncomplicated ABRS. Imaging should be reserved for pts who develop recurrent ABRS, complicated RS, or chronic RS w/ atypical sx, or for defining sinus anatomy prior to surgery. In adults, clinical evaluation combined w/ nasal endoscopy may obviate the need for CT imaging in some cases of chronic RS. ***Radiography:*** Radiographs are limited in the evaluation of the paranasal sinuses because they cannot localize the pathology well and cannot evaluate the ostiomeatal complex. Sinus radiographs are inaccurate in a high % of pts and have been supplanted by CT imaging. ***CT:*** CT scans are the gold standard for guiding management of RS because they accurately depict the sinus anatomy and complications. Contrast enhancement is not generally needed for routine sinus imaging. CT is the study of choice in children w/ persistent, recurrent, or chronic RS. If suspicion exists for complications of RS, then intravenous contrast CT, including the brain and sinuses, is indicated. ***MRI:*** Not as good as CT for depicting bone details but more sensitive for evaluating intracranial complications not demonstrated on initial CT scan. MRI of the sinuses			experts, guideline review and update process not described, competing interests of grp members not declared)

Sponsor, Title	Relevant Recommendations			Quality/Main Limitations
	Diagnosis	Treatment	Repeat Testing	
	should not be the primary imaging for evaluation of RS. ***Fungal RS:*** Invasive fungal RS is a rapidly progressive disease seen in immunosuppressed pts and poorly controlled diabetics. Both CT (w/ contrast) and MRI (w/ or w/o contrast) of the sinuses, brain, and orbits may be needed to fully define the extent of orbital or intracranial extension of disease. ***Suspected Sinonasal Mass:*** If seen on sinus CT or if pts have persistent sx of pain, nasal obstruction, or epistaxis, complete evaluation of the extent of disease usually requires both CT and MRI evaluation.			
Institute for Clinical Systems Improvement (ICSI) (Snellman et al., 2013) *Diagnosis and Treatment of Respiratory Illness in Children and Adults*	***Presumed ABRS:*** URI present ≥10 days w/o improvement; sx are severe or pt has fever ≥102°F w/ purulent nasal discharge or facial pain that lasts ≥3-4 days; sx are worsening or new onset of fever, headache, or increased nasal discharge after initial improvement Gold standard for dx of ABRS: Sinus aspiration (>10,000 colony-forming units/mL). However, routine sinus aspiration is not practical. ***Presumed allergic RS:*** Pruritus of eyes, nose, palate, ears; watery rhinorrhea; sneezing; seasonal sx; family hx of allergies; sensitivity to specific allergens; asthma or eczema Reassessment: An alternative management strategy is recommended if sx worsen after 48-72 hrs of initial Abx tx or fail to improve despite 3-5 days of initial empiric Abx tx. ***Imaging:*** Not to be used for dx of ABRS Reassessment: X-ray, although nonspecific due to many false-positives, is fairly sensitive in detecting maxillary sinusitis. An abnormal sinus x-ray, especially if opacification or an air-fluid level is present, suggests ABRS. A sinus CT scan could also be obtained to verify disease. It is somewhat more expensive, but has greater accuracy and is often recommended as the imaging test of choice. Failure of Abx tx: If no response to 3 wks of Abx tx, consider limited coronal CT scan of sinuses and/or referral to specialist.	***Abx for ABRS:*** Abx for pts who failed decongestant tx; have sx of more severe illness; have complications of acute RS. Amoxicillin-clavulanate is considered first-line tx. The duration of Abx tx is controversial, ranging 3-14 days. ***Reassessment*:** If sx worsen after 48-72 hrs of initial Abx tx or fail to improve despite 3-5 days of initial empiric Abx tx, either: (1) switch to second-line Abx, (2) refer to specialist, (3) reinforce comfort and prevention measures. If pt has no or little sx improvement after 10-day course of Abx tx, either treat w/ (1) high-dose amoxicillin-clavulanate, (2) cephalosporin w/ intramuscular ceftriaxone, (3) fluoroquinolone w/ pneumococcal coverage (except for pts who are skeletally immature)	No recommendations	4—Fair (systematic search methods and criteria for selecting evidence not described, strength of recommendations not given, methods for formulating recommendations not described, guideline not reviewed by external experts)

Sponsor, Title	Relevant Recommendations			Quality/Main Limitations
	Diagnosis	Treatment	Repeat Testing	
Infectious Diseases Society of America (IDSA) (Chow et al., 2012) *IDSA Clinical Practice Guideline for Acute Bacterial Rhinosinusitis in Children and Adults*	***Presumed ABRS:*** Diagnose ABRS vs VRS when pt presents w/ (a) persistent sx lasting ≥10 days w/o improvement, (b) severe sx or high fever (≥39°C/102°F), (c) worsening sx after initial improvement. *Strong recommendation* Reassessment: An alternative management strategy is recommended if sx worsen after 48-72 hrs of initial Abx tx or fail to improve despite 3-5 days of initial empiric Abx tx. *Strong recommendation* Histopathology: Obtain cultures by direct sinus aspiration rather than by nasopharyngeal swab in pts who have failed to respond to Abx tx. *Strong recommendation* ***Imaging:*** Dx: *Not* recommended to distinguish ABRS from VRS. *Weak recommendation against* Suspected complications: Axial and coronal views of contrast-enhanced CT rather than MRI to localize the infection and to guide further tx. *Weak recommendation*	***Abx tx for ABRS:*** Initiated as soon as the clinical dx of ABRS is made. *Strong recommendation* Amoxicillin-clavulanate rather than amoxicillin alone is recommended as antimicrobial tx for ABRS in children. *Strong recommendation* Amoxicillin-clavulanate rather than amoxicillin alone is recommended as antimicrobial tx for ABRS in adults. *Weak recommendation* Abx tx duration: 5-7 days for uncomplicated ABRS in adults; 10-14 days in children. *Weak recommendation* Intranasal saline irrigation is recommended as an adjunctive tx in adults w/ ABRS. *Weak recommendation* Intranasal corticosteroids are recommended as an adjunct tx, primarily in pts w/ a hx of AR. *Weak recommendation* Topical and oral decongestants and/or antihistamines are *not* recommended as adjunctive tx in pts w/ ABRS. *Strong recommendation against*	No recommendations	6—Good (literature search was limited to systematic reviews; several panel members served as consultants or received research funding from pharmaceutical companies)

CLINICAL COMMITTEE FINDINGS AND DECISIONS

Efficacy Considerations

- What is the evidence that use of the technology results in more beneficial, important health outcomes? Consider:
  - Direct outcome or surrogate measure
  - Short term or long term effect
  - Magnitude of effect
  - Impact on pain, functional restoration, quality of life
  - Disease management
- What is the evidence confirming that use of the technology results in a more beneficial outcome, compared to no treatment or placebo treatment?
- What is the evidence confirming that use of the technology results in a more beneficial outcome, compared to alternative treatment?
- What is the evidence of the magnitude of the benefit or the incremental value?
- Does the scientific evidence confirm that use of the technology can effectively replace other technologies or is this additive?
- For diagnostic tests, what is the evidence of a diagnostic tests' accuracy?
  - Does the use of the technology more accurately identify both those with the condition being evaluated and those without the condition being evaluated?
- Does the use of the technology result in better sensitivity and better specificity?
- Is there a tradeoff in sensitivity and specificity that on balance the diagnostic technology is thought to be more accurate than current diagnostic testing?
- Does use of the test change treatment choices?

Safety

- What is the evidence of the effect of using the technology on significant morbidity?
  - Frequent adverse effect on health, but unlikely to result in lasting harm or be life-threatening, or;
  - Adverse effect on health that can result in lasting harm or can be life-threatening?
- Other morbidity concerns?
- Short term or direct complication versus long term complications?
- What is the evidence of using the technology on mortality – does it result in fewer adverse non-fatal outcomes?

Cost Impact

- Do the cost analyses show that use of the new technology will result in costs that are greater, equivalent or lower than management without use of the technology?

Overall

- What is the evidence about alternatives and comparisons to the alternatives?
- Does scientific evidence confirm that use of the technology results in better health outcomes than management without use of the technology?

Next Step: Cover or No Cover

If not covered, or covered unconditionally, the Chair will instruct staff to write a proposed findings and decision document for review and final adoption at the following meeting.

Next Step: Cover with Conditions

If covered with conditions, the Committee will continue discussion.

1) Does the committee have enough information to identify conditions or criteria?

- Refer to evidence identification document and discussion.
- Chair will facilitate discussion, and if enough members agree, conditions and/or criteria will be identified and listed.
- Chair will instruct staff to write a proposed findings and decision document for review and final adoption at next meeting.

2) If not enough or appropriate information, then Chair will facilitate a discussion on the following:

- What are the known conditions/criteria and evidence state
- What issues need to be addressed and evidence state

The chair will delegate investigation and return to group based on information and issues identified. Information known but not available or assembled can be gathered by staff ; additional clinical questions may need further research by evidence center or may need ad hoc advisory group; information on agency utilization, similar coverage decisions may need agency or other health plan input; information on current practice in community or beneficiary preference may need further public input. Delegation should include specific instructions on the task, assignment or issue; include a time frame; provide direction on membership or input if a group is to be convened.

Clinical Committee Evidence Votes

First Voting Question

The HTCC has reviewed and considered the technology assessment and information provided by the administrator, reports and/or testimony from an advisory group, and submissions or comments from the public. The committee has given greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

Is there sufficient evidence under some or all situations that the technology is:

	Unproven (no)	Equivalent (yes)	Less (yes)	More (yes)
Effective				
Safe				
Cost-effective				

Discussion

Based on the evidence vote, the committee may be ready to take a vote on coverage or further discussion may be warranted to understand the differences of opinions or to discuss the implications of the vote on a final coverage decision.

- Evidence is insufficient to make a conclusion about whether the health technology is safe, efficacious, and cost-effective;
- Evidence is sufficient to conclude that the health technology is unsafe, ineffectual, or not cost-effective
- Evidence is sufficient to conclude that the health technology is safe, efficacious, and cost-effective for all indicated conditions;
- Evidence is sufficient to conclude that the health technology is safe, efficacious, and cost-effective for some conditions or in some situations

A straw vote may be taken to determine whether, and in what area, further discussion is necessary.

Second Vote

Based on the evidence about the technologies' safety, efficacy, and cost-effectiveness, it is

____Not Covered _____Covered Unconditionally ____ Covered Under Certain Conditions

Discussion Item

Is the determination consistent with identified Medicare decisions and expert guidelines, and if not, what evidence is relied upon.

Next Step: Proposed Findings and Decision and Public Comment

At the next public meeting the committee will review the proposed findings and decision and consider any public comments as appropriate prior to a vote for final adoption of the determination.

1) Based on public comment was evidence overlooked in the process that should be considered?

2) Does the proposed findings and decision document clearly convey the intended coverage determination based on review and consideration of the evidence?

Next Step: Final Determination

Following review of the proposed findings and decision document and public comments:

Final Vote

Does the committee approve the Findings and Decisions document with any changes noted in discussion?

If yes, the process is concluded.

If no, or an unclear (i.e., tie) outcome Chair will lead discussion to determine next steps.