Washington State Health Care Authority

Health Technology Assessment Program

Selected technologies 2023

Contents

- ☐ Director's selection letter
- ☐ Topic selection background information
- ☐ Public comments received and HTA program response

STATE OF WASHINGTON
HEALTH CARE AUTHORITY
626 8th Avenue, SE • P.O. Box 45502 • Olympia, Washington 98504-5502

June 29, 2023

To whom it may concern:

SUBJECT: Health Technology Assessment Topic Selection, 2023

As the Director of the Health Care Authority, I select technologies for review by Health Technology Clinical Committee in consultation with other agencies and the Committee itself (70.14 RCW). Technologies are selected when there are concerns about safety, efficacy or value (cost-effectiveness), when state expenditures are or could be high, and when there is adequate evidence to conduct a review. Technologies are selected for rereview when new evidence is available that could change a previous determination.

For the current selection cycle, I reviewed the proposed topics and the comments received from interested individuals and groups who responded in the public comment period (June 12 to June 26). Based on this review I have selected the following technologies for assessment:

	Primary criteria ranking		
Technology	**Safety**	**Efficacy**	**Cost**
Whole Genome Sequencing	**High**	**Medium**	**High**
Whole genome sequencing (WGS) is a laboratory test utilized to determine the arrangement (sequence) of an individual's entire genome at a single time. WGS would focus on patients who present with clinical features suspicious for genetic etiology but with no specific diagnosis. Petition for review submitted by stakeholder.			
Treatments for chondral defects of the knee	**High**	**Medium**	**High**
Treatments to include in review for patients with chondral defects of the knee would be matrix-induced autologous chondrocyte implantation (MACI), autologous chondrocyte implantation (ACI), microfracture surgery, and osteochondral autologous transplantation (OATS) as potential alternatives to surgical knee cartilage repair strategy.			
Bariatric Surgery	**Medium**	**High**	**High**
Bariatric surgery refers to a collective group of procedures that involve modifications to the digestive system that promote weight loss. This rereview would look to expand the scope to include four types of procedures not included in the last rereview conducted in 2015: gastric bypass, gastric banding, sleeve gastrectomy, and biliopancreatic diversion (with or without duodenal switch).			

Vertebroplasty, Kyphoplasty, and Sacroplasty	**High**	**High**	**Medium**

Vertebroplasty involves injection of bone cement into a partially collapsed vertebral body, while kyphoplasty involves expansion of the partially collapsed vertebral body with an inflatable bone tamp, in an effort to relieve pain and provide stability. Sacroplasty involves surgical treatment that attempts to repair sacral insufficiency fractures using bone cement. HTCC first reviewed in 2011 with the most recent rereview conducted in 2019.

At this time, **hip surgery for femoroacetabular impingement syndrome (FAI)**, which was first reviewed in 2011 and rereviewed in 2019, is pending further review through a literature scan. The HTA program will continue to monitor the literature on this topic.

Upon publication of the selected list of technologies, a 30-day comment period will begin whereby any interested person or group may provide information to be considered in the review of the selected topic(s).

Should you have any questions or concerns, please contact the HTA Program at shtap@hca.wa.gov.

Sincerely,

Susan E. Birch MBA, BSN, RN
Director

Washington State Health Care Authority

Technology assessment background summary

New proposed technologies

Technology	Primary criteria ranking		
	Safety	Efficacy	Cost
Whole Genome Sequencing	**High**	**Medium**	**High**
Whole genome sequencing (WGS) is a laboratory test utilized to determine the arrangement (sequence) of an individual's entire genome at a single time. WGS would focus on patients who present with clinical features suspicious for genetic etiology but with no specific diagnosis. Petition for review submitted by stakeholder.			
Treatments for chondral defects of the knee	**High**	**Medium**	**High**
Treatments to be include in review for patients with chondral defects of the knee to include matrix-induced autologous chondrocyte implantation (MACI), autologous chondrocyte implantation (ACI), microfracture surgery, and osteochondral autologous transplantation (OATS) as potential alternatives to surgical knee cartilage repair strategy.			

Topics considered, not proposed

	Technology
1	Genetic testing for cancer patients
2	Vision therapy
3	Catheter ablation procedures for supraventricular tachyarrhythmia (SVTA)
4	Functional neuroimaging for primary degenerative dementia and mild cognitive impairment
5	Hyperthermic intraperitoneal chemotherapy (HIPEC)

Washington State Health Care Authority

Rereview technologies

Technologies are considered for rereview at least once every eighteen months based on availability of new evidence that may change the decision. All technologies with determinations beyond 18 months since the final determination previously reviewed by the Health Technology Clinical Committee (HTCC) are listed below, along with information on whether they have been selected for rereview.

	Technology	HTCC review history	Rereview?
1	**Bariatric Surgery** Expand scope to include four types of procedure.	HTCC first reviewed in 2007 with a rereview conducted in 2015.	Yes
2	**Vertebroplasty, Kyphoplasty, and Sacroplasty**	Literature scan conducted in 2016, 2017, & 2020. HTCC first reviewed in 2011.	Yes
3	**Hip surgery for Femoroacetabular impingement syndrome (FAI)** Formal literature scan in process to determine if new evidence is available.	HTCC first reviewed in 2011 with a rereview conducted in 2019. Literature scan conducted in 2014 & 2018.	Pending
4	**Cochlear Implants (CI)** Petition for rereview received, but limited evidence base available, determined that an updated internal policy would support Washington state residents impacted by single sided deafness where CI is appropriate.	HTCC first reviewed in 2013.	No

For the current period, the program has not received or identified new evidence to support review of the following:

	HTA Decisions	Latest Review/ Scan
1	Applied Behavioral Analysis (ABA or ABA Therapy) Based Behavioral Interventions for the Treatment of Autism Spectrum Disorder	June 2011
2	Appropriate Imaging for Breast Cancer Screening in Special Populations	January 2015
3	Artificial Disc Replacement	January 2017
5	Bone Growth Stimulation	August 2009
6	Bone Morphogenic Proteins for Use in Lumbar Fusion	March 2012
7	Breast MRI	August 2010
8	Bronchial Thermoplasty for Asthma	May 2016
9	Cardiac Stents	January 2016
10	Carotid Artery Stenting	September 2013
11	Catheter Ablation Procedures for Supraventricular Tachyarrhythmia (SVTA) Including Atrial Flutter, Atrial Fibrillation	May 2013

	HTA Decisions	Latest Review/ Scan
12	Cell-Free DNA Prenatal Screening for Chromosomal Aneuploidies (cfDNA)	January 2020
13	Cervical Spinal Fusion for Degenerative Disc Disease	March 2013
14	Cochlear Implants: Bilateral Versus Unilateral	May 2013
15	Computed Tomographic Colonography (CTC)	February 2008
16	Continuous Glucose Monitoring	January 2018
17	Coronary Artery Calcium Scoring	May 2020
18	Discography	February 2008
19	Electrical Neural Stimulation (ENS)	October 2009
20	Extracorporeal Membrane Oxygenation Therapy (ECMO)	March 2016
21	Extracorporeal Shock Wave Therapy (ESWT) for Musculoskeletal Conditions	March 2017
22	Facet Neurotomy	June 2020
23	Fecal Microbiota Transplantation	November 2016
24	Functional Neuroimaging for Primary Degenerative Dementia and Mild Cognitive Impairment	January 2015
25	Gene Expression Profile Testing of Cancer Tissue	March 2018
26	Genomic Microarray Testing	January 2018
27	Hip Resurfacing	November 2013
28	Hip Surgery for Femoroacetabular Impingement (FAI) Syndrome	November 2019
29	Hyperbaric Oxygen Therapy (HBOT) for Tissue Damage Including Wound Care and Treatment of Central Nervous System (CNS) Conditions	March 2013
30	Imaging for Rhinosinusitis	May 2015
31	Implantable Drug Delivery System for Chronic Non-Cancer Pain	August 2008
32	Intensity Modulated Radiation Therapy (IMRT)	September 2012
33	Knee Arthroscopy for Osteoarthritis of the Knee	August 2008
34	Lumbar Fusion for Degenerative Disc Disease	November 2015
35	Microprocessor-Controlled Lower Limb Prosthetics	November 2011
36	Negative Pressure Wound Therapy (NPWT) for Home Use	November 2016
37	Nonpharmacologic Treatments for Treatment Resistant Depression	March 2014
38	Peripheral Nerve Ablation for Limb Pain	January 2019
39	Pharmacogenetic Testing for Patients Being Treated with Oral Anticoagulants	May 2018
40	Pharmacogenomic Testing for Selected Conditions	January 2017
41	Positron Emission Tomography (PET) Scans for Lymphoma	November 2018

	HTA Decisions	Latest Review/ Scan
42	Proton Beam Therapy	May 2019
43	Robotic Assisted Surgery (RAS)	May 2012
44	Routine Ultrasound for Pregnancy	November 2010
45	Screening & Monitoring Tests for Osteopenia/Osteoporosis	November 2014
46	Selected Treatments for Varicose Veins	May 2017
47	Sleep Apnea Diagnosis and Treatment in Adults	March 2012
48	Spinal Injections	March 2016
49	Stem Cell Therapy for Musculoskeletal Conditions	June 2020
50	Surgery for Lumbar Radiculopathy/Sciatica	May 2018
51	Testosterone Testing	March 2015
52	Tinnitus: Non-Invasive, Non-Pharmacologic Treatments	May 2020
53	Total Knee Arthroplasty	October 2010
54	Tumor Treating Fields (Optune)	November 2018
55	Tympanostomy Tubes in Children	November 2015
56	Upper Endoscopy for GERD and GI symptoms	May 2012
57	Upright /Positional MRI	June 2012
58	Vagal Nerve Stimulation for Epilepsy and Depression	May 2020
59	Vitamin D Screening and Testing	November 2012
60	Whole Exome Sequencing	November 2019

Response to public comments

This document responds to comments received on the prospective 2024 HTA technology topics. Public comments were accepted from June 12 through June 26, 2023. Comments focused on four proposed topics: **Whole genome sequencing, treatments for chondral defects of the knee, bariatric surgery, and vertebroplasty, kyphoplasty, and sacroplasty.** All comments were presented to the Director for consideration. The Director did not select **cochlear implants** for rereview at this time. The Director is considering **whole genome sequencing, treatments for chondral defects of the knee, bariatric surgery, and vertebroplasty, kyphoplasty, and sacroplasty**, pending further review of the evidence received during the public comment period. Comments received during the public comment period are included in this document.
Public comments were received from these individuals and groups:

	Commenter	Topic
1	**Erika Beckman**, Licensed, Certified Genetic Counselor, Biochemical Genetics, Seattle Children's	Whole Genome Sequencing
2	**James Bennett**, Associate Professor, Division Genetic Medicine, Department of Pediatrics, University of Washington, Assistant Director, Molecular Diagnostics, Seattle Children's Hospital	Whole Genome Sequencing
3	**Wendy Chan**, MHA, Vice President, Health Economic, Policy and Reimbursement	Vertebroplasty, Kyphoplasty, Sacroplasty
4	**Jessie Conta,** Licensed Genetic Counselor, Owner – Pickhandle Consulting LLC	Whole Genome Sequencing
5	**Katrina M Dipple,** MD, PhD	Whole Genome Sequencing
6	**John L. Fox,** MD, MHA, Senior Medical Director for the Americas, Market Access, Illumina	Whole Genome Sequencing
7	**Jon Hassler,** Sr. Policy and Payer Relations Analyst, Payer Relations, Labcorp	Whole Genome Sequencing
8	**Susan Hupp,** Senior Manager, Reimbursement and Payer Solutions, Medtronic	Bariatric surgery
9	**Mei Li,** Program Coordinator, Department of Laboratory Medicine and Pathology University of Washington **Geoffrey S. Baird,** MD, PhD, Professor and Chair, Paul E. Strandjord and Kathleen J. Clayson Endowed Chair, Department of Laboratory Medicine and Pathology	Whole Genome Sequencing
10	**Kerry Lorenzo,** MS, LGC, Genetic Counselor, Prenatal Diagnosis and Treatment Program, Pediatric Genetics, Seattle Children's Tri-Cities	Whole Genome Sequencing
11	**Jamie Love-Nichols,** MS, MPH, CGC, Licensed, Certified Genetic Counselor, Genetic Counselor Supervisor, Genetic Medicine, Seattle Children's Hospital	Whole Genome Sequencing

	Commenter	Topic
12	**Lauren Lulis,** MS, LCGC, Genetic Counselor, Genetic Test Utilization Program Manager, Children's Hospital of Philadelphia	Whole Genome Sequencing
13	**Ashley Maleki,** CPC, CPMA, Senior Manager, Health Policy and Economics, Society of Interventional Radiology	Vertebroplasty, Kyphoplasty, Sacroplasty
14	**Maria Mills,** MS, CGC, Genetic Counselor, Craniofacial Medicine & Biochemical Genetics, Seattle Children's Hospital	Whole Genome Sequencing
15	**Spencer Parr,** Attorney – Partner, Washington Law Center	Treatments for chondral defects of the knee
16	**Abbey Scott,** CGC, Inpatient Genetic Counselor III, Seattle Children's Hospital	Whole Genome Sequencing
17	**Kiana Siefkas,** MS, LGC, Lead Genetic Counselor, Prenatal Diagnosis and Treatment Program, Seattle Children's	Whole Genome Sequencing
18	**Sarah Soto,** MS, CGC, Medical Policy Impact and Payer Evidence Strategy, Market Access, GeneDx **Paul Kruszka,** MD, FACMG, Chief Medical Officer, GeneDx	Whole Genome Sequencing
19	**Monica Wellner,** Laboratory Director, Specialty Laboratories and Programs, Director of Operations, PLUGS, Seattle Children's	Whole Genome Sequencing
20	**Megan Yabumoto,** MS, CGC, Licensed, Genetic Counselor, Medical Genetics, Seattle Children's Hospital	Whole Genome Sequencing

A summary of comments received and HTA responses are contained in the table below**.** The full text of all comments, references and attachments follows.

Commenter	Topic	Comment	HTA program response
Erika Beckman, Licensed, Certified Genetic Counselor, Biochemical Genetics, Seattle Children's	Whole Genome Sequencing	Complete comments included below.	Thank you for providing comment and evidence for this proposed review. All information provided will be considered in any future review of whole genome sequencing.
James Bennett, Associate Professor, Division Genetic Medicine, Department of Pediatrics, University of Washington, Assistant Director, Molecular Diagnostics, Seattle Children's Hospital	Whole Genome Sequencing	Complete comments included below.	Thank you for providing comment and evidence for this proposed review. All information provided will be considered in any future review of whole genome sequencing.
Wendy Chan, MHA, Vice President, Health Economic, Policy and Reimbursement	Vertebroplasty, Kyphoplasty, Sacroplasty	Complete comments included below.	Thank you for providing comment and evidence for this proposed rereview. All information provided will be considered in any future rereview of vertebroplasty, kyphoplasty, and sacroplasty.
Jessie Conta, Licensed Genetic Counselor, Owner – Pickhandle Consulting LLC	Whole Genome Sequencing	Complete comments included below.	Thank you for providing comment and evidence for this proposed review. All information provided will be considered in any future review of whole genome sequencing.
Katrina M Dipple, MD, PhD	Whole Genome Sequencing	Complete comments included below.	Thank you for providing comment and evidence for this proposed review. All information provided will be considered in any future review of whole genome sequencing.
John L. Fox, MD, MHA, Senior Medical Director for the Americas, Market Access, Illumina	Whole Genome Sequencing	Complete comments included below.	Thank you for providing comment and evidence for this proposed review. All information provided will be considered in any future review of whole genome sequencing.
Jon Hassler, Sr. Policy and Payer Relations Analyst, Payer Relations, Labcorp	Whole Genome Sequencing	Partial comments included below. Submitted letter in support of whole genome sequencing. The letter is password protected without the ability to redact personal	Thank you for providing comment and evidence for this proposed review. All information provided will be considered in any future review of whole genome sequencing.

Commenter	Topic	Comment	HTA program response
		information and therefore is not included below.	
Susan Hupp, Senior Manager, Reimbursement and Payer Solutions, Medtronic	Bariatric surgery	Complete comments included below.	Thank you for providing comment and evidence for this proposed rereview. All information provided will be considered in any future rereview of bariatric surgery.
Mei Li, Program Coordinator, Department of Laboratory Medicine and Pathology University of Washington **Geoffrey S. Baird,** MD, PhD, Professor and Chair, Paul E. Strandjord and Kathleen J. Clayson Endowed Chair, Department of Laboratory Medicine and Pathology	Whole Genome Sequencing	Complete comments included below.	Thank you for providing comment and evidence for this proposed review. All information provided will be considered in any future review of whole genome sequencing.
Kerry Lorenzo, MS, LGC, Genetic Counselor, Prenatal Diagnosis and Treatment Program, Pediatric Genetics, Seattle Children's Tri-Cities	Whole Genome Sequencing	Complete comments included below.	Thank you for providing comment and evidence for this proposed review. All information provided will be considered in any future review of whole genome sequencing.
Jamie Love-Nichols, MS, MPH, CGC, Licensed, Certified Genetic Counselor, Genetic Counselor Supervisor, Genetic Medicine, Seattle Children's Hospital	Whole Genome Sequencing	Complete comments included below.	Thank you for providing comment and evidence for this proposed review. All information provided will be considered in any future review of whole genome sequencing.
Lauren Lulis, MS, LCGC, Genetic Counselor, Genetic Test Utilization Program Manager, Children's Hospital of Philadelphia	Whole Genome Sequencing	Complete comments included below.	Thank you for providing comment and evidence for this proposed review. All information provided will be considered in any future review of whole genome sequencing.
Ashley Maleki, CPC, CPMA, Senior Manager, Health Policy and Economics, Society of Interventional Radiology	Vertebroplasty, Kyphoplasty, Sacroplasty	Complete comments included below.	Thank you for providing comment and evidence for this proposed rereview. All information provided will be considered in any future rereview of vertebroplasty, kyphoplasty, and sacroplasty.

Commenter	Topic	Comment	HTA program response
Maria Mills, MS, CGC, Genetic Counselor, Craniofacial Medicine & Biochemical Genetics, Seattle Children's Hospital	Whole Genome Sequencing	Complete comments included below.	Thank you for providing comment and evidence for this proposed review. All information provided will be considered in any future review of whole genome sequencing.
Spencer Parr, Attorney – Partner, Washington Law Center	Treatments for chondral defects of the knee	Complete comments included below.	Thank you for providing comment and evidence for this proposed topic, which includes OATS. The program appreciates your perspective and the time you took to share personal cases you have represented.
Abbey Scott, CGC, Inpatient Genetic Counselor III, Seattle Children's Hospital	Whole Genome Sequencing	Complete comments included below.	Thank you for providing comment and evidence for this proposed review. All information provided will be considered in any future review of whole genome sequencing.
Kiana Siefkas, MS, LGC, Lead Genetic Counselor, Prenatal Diagnosis and Treatment Program, Seattle Children's	Whole Genome Sequencing	Complete comments included below.	Thank you for providing comment and evidence for this proposed review. All information provided will be considered in any future review of whole genome sequencing.
Sarah Soto, MS, CGC, Medical Policy Impact and Payer Evidence Strategy, Market Access, GeneDx **Paul Kruszka,** MD, FACMG, Chief Medical Officer, GeneDx	Whole Genome Sequencing	Complete comments included below.	Thank you for providing comment and evidence for this proposed review. All information provided will be considered in any future review of whole genome sequencing.
Monica Wellner, Laboratory Director, Specialty Laboratories and Programs, Director of Operations, PLUGS, Seattle Children's	Whole Genome Sequencing	Complete comments included below.	Thank you for providing comment and evidence for this proposed review. All information provided will be considered in any future review of whole genome sequencing.
Megan Yabumoto, MS, CGC, Licensed, Genetic Counselor, Medical Genetics, Seattle Children's Hospital	Whole Genome Sequencing	Complete comments included below.	Thank you for providing comment and evidence for this proposed review. All information provided will be considered in any future review of whole genome sequencing.

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: Support for WA HTA Review of WGS
Date: Monday, June 26, 2023 1:58:15 PM
Attachments: [redacted]

External Email

To Whom it May Concern:

I am writing in support of the proposed HTA review of whole genome sequencing (WGS) for 2024.

There has been substantial evidence published evaluating WGS in patients with suspected genetic diseases demonstrating the clinical utility and positive impact on health outcomes of this technology. Over 750,000 Washingtonians have a rare disease and approximately 80% of rare diseases have a genetic cause. We know that the average diagnostic odyssey for these patients includes 8 specialists, takes 5-7 years, and costs $19K in testing, with misdiagnoses along the way.

Our organization is a member of PLUGS (schplugs.org), a not-for-profit national laboratory test stewardship network, which helps guides utilization of medically appropriate genetic tests. Genetic testing has historically followed a stepwise process, one test at a time, with hope that providers are able to select the best first test - which is time-consuming and costly, and many times doesn't provide an answer. Whole genome sequencing combines many tests into one and offers the best available diagnostic option for many individuals with undiagnosed rare disease. Think of it like upgrading to the newest smartphone technology and retiring the multiple devices you used before. Access to WGS in Washington ensures that the best tool can be used to end the diagnostic odyssey in specific circumstances.

We strongly recommend that the Director select this topic for HTA review in 2024.

Sincerely,

Erika Beckman, MS, CGC (*she/her/hers*)
Licensed, Certified Genetic Counselor | Biochemical Genetics
Seattle Children's
[redacted]
www seattlechildrens.org

Connect with us online:

From: [redacted]
To:
Subject: Support for WA HTA Review of WGS
Date: Monday, June 26, 2023 10:38:13 AM

External Email

To Whom it May Concern:

I am writing in support of the proposed HTA review of **whole genome sequencing** (WGS) for 2024.

There is substantial published evidence evaluating WGS in patients with suspected genetic diseases demonstrating the clinical utility and positive impact on health outcomes of this technology. Over 750,000 Washingtonians have a rare disease and approximately 80% of rare diseases have a genetic cause. We know that the average diagnostic odyssey for these patients includes 8 specialists, takes 5-7 years, and costs $19K in testing, with misdiagnoses along the way.

On a personal note, as an MD geneticist who cares for patients with rare disease, I see the potential for lives improved every day with greater access to genome sequencing. Washington State has traditionally been a leader in the fields of technology and healthcare, and this would be a major win for Washington Health Care Authority amongst its peers at other states.

Genetic testing has historically followed a stepwise process, one test at a time, with hope that providers are able to select the best first test - which is time-consuming and costly, and many times doesn't provide an answer. Whole genome sequencing combines many tests into one and offers the best available diagnostic option for many individuals with undiagnosed rare disease. Think of it like upgrading to the newest smartphone technology and retiring the multiple devices you used before. Access to WGS in Washington ensures that the best tool can be used to end the diagnostic odyssey in specific circumstances.

I strongly recommend that the Director select this topic for HTA review

in 2024.

Sincerely,
Jimmy

James T Bennett, MD PhD
Associate Professor, Division Genetic Medicine
Department of Pediatrics, University of Washington
Assistant Director, Molecular Diagnostics, Seattle Children's Hospital
Brotman Baty Institute for Precision Medicine
Center for Developmental Biology and Regenerative Medicine
[redacted]

Hamann, Valerie (HCA)

From: Chan, Wendy [redacted]
Sent: Monday, June 19, 2023 9:04 AM
To: HCA ST Health Tech Assessment Prog
Cc: Ricker, Christine; Myszka, Nate
Subject: Medtronic Public Comment on Vertebroplasty, Kyphoplasty, and Sacroplasty Review Opening
Attachments: MDT_WA State HTA VCF Comments_2023.pdf

Importance: High

External Email

Hello WA State HTA,

Please refer to attached comments from Medtronic requesting re-review of vertebral compression fracture procedures (Vertebroplasty, Kyphoplasty, and Sacroplasty). We strongly believe that the new evidence warrants review and reconsideration of the 2020 original decision.

We look forward to providing input into this process when this HTA review becomes open and warrants additional stakeholder perspective from local KOLS and the specialty societies.

Please let me or Christine Ricker know if you have questions.

Thank you for the opportunity to comment.

Best, Wendy Chan

Wendy Chan, MHA
Vice President, Health Economics, Policy and Reimbursement

Medtronic
Neuromodulation, Pelvic Health, & Neurovascular

[redacted]

Medtronic

June 19, 2023

Via online submission at: shtap@hca.wa.gov

RE: State of WA Health Care Authority- 2023 HTA Public Comment on Vertebroplasty, Kyphoplasty, Sacroplasty Re-Review

Dear Health Technology Clinical Committee,

We are writing to provide support for the re-review of vertebroplasty, kyphoplasty, and sacroplasty for the treatment of vertebral compression fractures (VCF) since the last review of evidence in 2020.

Access to these therapies today is broad, with WA state one of the only coverage entities not considering the evidence sufficient for treatment. Medicare Administrative Contractors (MACs) recently updated their Local Coverage Determinations (LCDs) concerning coverage criteria for the treatment of VCFs in 2021.[1-8] All LCDs cover immediate access to vertebroplasty or kyphoplasty for patients that meet medical necessity criteria.[1-8] In the evidence summaries of these LCDs the MACs reference all prior randomized controlled trials (RCTs) and associated considerations that the WA HTA reviews have previously highlighted; but also review the breadth of evidence available inclusive of recent mortality data, guidelines, and a clinical care pathway created by a multispecialty expert panel.

We support the re-review of vertebroplasty, kyphoplasty, and sacroplasty. We respectfully request that the following bodies of evidence be included in the next PICOS literature search criteria:

- Evidence related to mortality risk following surgical intervention relative to conservative medical management.[9-15]
- Considerations related to oral opioid reduction, as shown in a large retrospective real-world data analysis.[16]
- Care pathway recommendations developed by a multi-specialty physician panel, developed using the RAND/UCLA Appropriateness Method.[17]
- Evidence-based national guidelines, with three of the four recommending surgical treatment.[18-21]
- Additional cost-effectiveness data that was potentially missed in the last re-review due to exact timing of the publication.[22]

We appreciate your consideration of our comments. If you have questions, feel free to reach out to me at [redacted] or Christine Ricker (Director, HEPR) at [redacted]

Sincerely,

Wendy Chan

Wendy Chan
Vice President, Health Economics Policy Reimbursement (HEPR), Neurosciences

References

1. CMS. L33569. Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF). https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33569&ver=28&keyword=vertebral%20compression%20fracture&keywordType=starts&areaId=all&docType=NCD,F&contractOption=all&sortBy=relevance&bc=1. Published 2021. Accessed June 19, 2023.

2. CMS. L34106. Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF). https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=34106&ver=46&keyword=vertebral%20compression%20fracture&keywordType=starts&areaId=all&docType=NCD,F&contractOption=all&sortBy=relevance&bc=1. Published 2021. Accessed Jun 19, 2023.

3. CMS. L34228. Percutaneous Vertebral Augmentation (PVA) for Osteoportotic Vertebral Compression Fracture (VCF). https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=34228&ver=51&keyword=vertebral%20compression%20fracture&keywordType=starts&areaId=all&docType=NCD,F&contractOption=all&sortBy=relevance&bc=1. Published 2021. Accessed June 19, 2023.

4. CMS. L38201. Percutaneous Vertebral Augmentation (PVA) for Vertebral Compression Fracture (VCF). https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=38201&ver=19&keyword=vertebral%20compression%20fracture&keywordType=starts&areaId=all&docType=NCD,F&contractOption=all&sortBy=relevance&bc=1. Published 2021. Accessed June 19, 2023.

5. CMS. L34976. Percutanteous Vertebral Aurgmentation (PVA) for Vertebral Compression Fracture (VCF). https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=34976&ver=34&keyword=vertebral%20compression%20fracture&keywordType=starts&areaId=all&docType=NCD,F&contractOption=all&sortBy=relevance&bc=1. Published 2021. Accessed June 19, 2023.

6. CMS. L35130. Percutaneous Vertebral Augmentation (PVA) for Vertebral Compression Fracture (VCF). https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=35130&ver=66&keyword=vertebral%20compression%20fracture&keywordType=starts&areaId=all&docType=NCD,F&contractOption=all&sortBy=relevance&bc=1. Published 2021. Accessed June 19, 2023.

7. CMS. L38737. Percutaneous Vertebral Augmentation (PVA) for Vertebral Compression Fracture (VCF). https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=38737&ver=11&keyword=vertebral%20compression%20fracture&keywordType=starts&areaId=all&docType=NCD,F&contractOption=all&sortBy=relevance&bc=1. Published 2021. Accessed June 19, 2023.

8. CMS. L38213. Percutaneous vertebral Augmentation (PVA) for Vertebral Compression Fracture (VCF). https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=38213&ver=9&keyword=vertebral%20compression%20fracture&keywordType=starts&areaId=all&docType=NCD,F&contractOption=all&sortBy=relevance&bc=1. Published 2021. Accessed June 19, 2023.

9. Chen AT, Cohen DB, Skolasky RL. Impact of nonoperative treatment, vertebroplasty, and kyphoplasty on survival and morbidity after vertebral compression fracture in the medicare population. *J Bone Joint Surg Am.* 2013;95(19):1729-1736.

10. Edidin AA, Ong KL, Lau E, Kurtz SM. Mortality risk for operated and nonoperated vertebral fracture patients in the medicare population. *J Bone Miner Res.* 2011;26(7):1617-1626.

11. Edidin AA, Ong KL, Lau E, Kurtz SM. Morbidity and Mortality After Vertebral Fractures: Comparison of Vertebral Augmentation and Nonoperative Management in the Medicare Population. *Spine (Phila Pa 1976).* 2015;40(15):1228-1241.

12. Hirsch JA, Chandra RV, Carter NS, Beall D, Frohbergh M, Ong K. Number Needed to Treat with Vertebral Augmentation to Save a Life. *AJNR Am J Neuroradiol.* 2020;41(1):178-182.

13. Lange A, Kasperk C, Alvares L, Sauermann S, Braun S. Survival and cost comparison of kyphoplasty and percutaneous vertebroplasty using German claims data. *Spine (Phila Pa 1976).* 2014;39(4):318-326.

14. McCullough BJ, Comstock BA, Deyo RA, Kreuter W, Jarvik JG. Major medical outcomes with spinal augmentation vs conservative therapy. *JAMA Intern Med.* 2013;173(16):1514-1521.

15. Ong KL, Beall DP, Frohbergh M, Lau E, Hirsch JA. Were VCF patients at higher risk of mortality following the 2009 publication of the vertebroplasty "sham" trials? *Osteoporos Int.* 2018;29(2):375-383.

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Hamann, Valerie (HCA)

From: Jessie Conta [redacted]
Sent: Thursday, June 22, 2023 9:57 AM
To: HCA ST Health Tech Assessment Prog
Cc: Dickerson, Jane
Subject: HTA Program Topic Review - WGS

External Email

To Whom it May Concern,

On behalf of the Seattle Children's Hospital Laboratory Stewardship program, we were pleased to see that review of whole genome sequencing (WGS) was proposed as a topic for review in 2024 by the Washington Health Technology Assessment program. We strongly recommend that the Director select this topic for HTA review in 2024.

There has been substantial evidence published evaluating WGS in patients with suspected genetic diseases demonstrating the clinical utility and positive impact on health outcomes of this technology. Over 750,000 Washingtonians have a rare disease and approximately 80% of rare diseases have a genetic cause. The diagnostic odyssey is defined as the time between when a symptom of a rare disease is first noted to the time when a final diagnosis is made. We know that the average diagnostic odyssey includes 8 specialists, takes 5-7 years, and costs $19K in diagnostic testing, with misdiagnoses along the way.

We have a long-standing laboratory stewardship program at Seattle Children's Hospital focused on utilization of medically appropriate genetic tests and responsible stewardship of limited resources. We've seen the evolution of genetic testing options and excitement felt by families and providers when a new technology helps solve a diagnostic mystery. Until recently, we followed a stepwise process, one test at a time, hoping we'd selected the best test first - which was time-consuming and costly, and many times didn't give us an answer. With improved coverage for exome sequencing supported by the HTA Program, we've been able to reduce the time to diagnosis and better support patients with rare genetic disease. Whole genome sequencing combines many tests into one and offers the best available diagnostic option for many individuals with undiagnosed rare disease - think of it like upgrading to the newest smartphone technology and retiring the multiple devices you used before – supporting access to WGS for individuals and families across the state ensures we can use the best tool to end the diagnostic odyssey in specific clinical circumstances.

Dr. Jane Dickerson (Division Head, Department of Laboratories, Seattle Children's & Director, Seattle Children's Laboratory Stewardship Program) is copied here, and both she and I can serve as primary points of contact for questions.

Thank you for your consideration and please let us know if we can provide additional information.

Kind regards,

Jessie

Jessie H. Conta, MS, CGC (she/her)
Licensed Genetic Counselor
Owner – Pickhandle Consulting LLC
[redacted]


PICKHANDLE
CONSULTING

From: [redacted]
To: [redacted]
Subject: Support of HTA review of WGS
Date: Monday, June 26, 2023 10:26:07 AM

External Email

To Whom it May Concern:

I am writing in support of the proposed HTA review of whole genome sequencing (WGS) for 2024.

There has been substantial evidence published evaluating WGS in patients with suspected genetic diseases demonstrating the clinical utility and positive impact on health outcomes of this technology. Over 750,000 Washingtonians have a rare disease and approximately 80% of rare diseases have a genetic cause. We know that the average diagnostic odyssey for these patients includes 8 specialists, takes 5-7 years, and costs $19K in testing, with misdiagnoses along the way.

As a clinical geneticist in WA state, I see many patients who would benefit from this testing. This is the current best and most comprehensive test available and would avoid step-wise testing which is time consuming and costly. Whole genome sequencing combines many tests into one and offers the best available diagnostic option for many individuals with undiagnosed rare disease. Think of it like upgrading to the newest smartphone technology and retiring the multiple devices you used before. Access to WGS in Washington ensures that the best tool can be used to end the diagnostic odyssey in specific circumstances.

I strongly recommend that the Director select this topic for HTA review in 2024.

Sincerely,
Katrina M Dipple, MD, PhD

From: Fox, John
To: HCA ST Health Tech Assessment Prog
Subject: Washington State HCA whole genome support letter from Illumina, Inc.
Date: Monday, June 26, 2023 2:53:29 PM
Attachments: image001.png
Washington State HCA whole genome support letter Illumina.docx

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External Email

Please accept this letter of support.

John

John L. Fox, MD MHA
Senior Medical Director for the Americas
Market Access
[redacted]

www.illumina.com

illumina®

2 June 2023

Washington State Health Care Authority
Sent to: shtap@hca.wa.gov

Subject: Prospective technology topics--2023
Illumina, Inc., thanks the Washington HTA for the ability to provide endorse to the Authority's review of whole genome sequencing. Illumina is the world's largest manufacturing of genomic sequencing platforms, including platforms that sequence both whole exomes and whole genomes. We believe the evidence and guidelines support the use of whole genome sequencing as a safe, timely, cost effective, and highest-yield test to diagnose infants and children with undiagnosable disease.

Genomic sequencing has transformed the diagnosis of infants and children with acute neonatal illnesses, congenital anomalies, seizure disorders, intellectual disabilities, and developmental delays. Historically, pediatric medical geneticists have been focused on dysmorphology. While the advent of karyotyping and chromosomal microarrays have increased the diagnostic yield from less than 5% to 8 to 10%, genomic sequencing can detect a causal genetic cause in up to 50% of children affected children. More importantly, many genetic disorders have a specific therapeutic intervention which in the absence of a diagnosis, is denied to patients. The application of genetic sequencing is considered to be comparable in societal benefit to separation of drinking and wastewater, the discovery of antibiotics, and surgical sterile technique.

As an aside, there is a need for clarification on covered services for both WES and WGS. Notably, the outpatient hospital fee schedule lists both WES and WGS as covered when billed by an HCA covered outpatient hospital (opps-20230401.xlsx).

Other healthcare entities, including health technology assessment companies, insurers, and laboratory benefits management companies have evaluated whole genome sequencing compared to chromosomal microarrays and whole exome sequencing. Several common concerns have been raised which are addressed below:

1. Concern: The published literature does not allow for strong conclusions to be drawn regarding the impact of whole genome sequencing on clinical outcomes for this population due to the significant variability in patient populations, study designs, and definitions of clinical management. Well-designed studies including primary clinical outcomes, such as improvements in quality of life or decreased rates of morbidity or mortality, are needed.
2. Illumina response: We agree that there will always be the desire for more data on clinical outcomes. The heterogeneity and the rarity of genetic diseases makes study of disease-specific clinical outcomes challenging.

   With that said, the definition of medical necessity in the Washington administrative code (WAC 182-500-0070) states ""a term for describing requested service which is reasonably calculated to prevent, diagnose, correct, cure, alleviate or prevent worsening of conditions in the client that endanger life, or cause suffering or pain, or result in an illness or infirmity, or threaten to cause or aggravate a handicap, or cause physical deformity or malfunction. There is no other equally effective, more conservative, or substantially less costly course of treatment available or suitable for the client requesting the service."

Based on this definition, whole genome sequencing would appear to be covered as an EPSDT benefit because it "can be reasonably calculated to diagnose conditions in the client that endanger life, or cause suffering or pain, or result in an illness or infirmity, or threaten to cause or aggravate a handicap or cause physical deformity or malformation." In addition, evidence supporting improved outcomes is challenging because of the rarity of specific genetic etiologies. That said, there is clear evidence that a genetic diagnosis changes management (see below).

Lastly, many health care decision makers cite the paucity of clinical outcome measures as a reason for not covering whole genome sequencing. The evidence supporting improved clinical outcomes is far superior to that of whole exome sequencing and yet WES is reimbursed by the HCA today. Was the decision to cover WES based on changes in clinical management or changes in outcomes? Either way, the data supporting genomes suggests it is a superior test to WES.

3. Concern: Benefits that accrue beyond the proband's diagnosis and treatment are not considered as part of a medical necessity determination and are not considered in the coverage process.
   Illumina's response: There are several advantages to genetic testing including:
   - Piece of mind that comes with establishment of a diagnosis
   - Identification of specific treatments
   - Ability to participate in a clinical trial if there are no approved therapies
   - Ending the diagnostic odyssey and additional testing
   - Reducing exposure of the child to unnecessary and invasive test (e.g., muscle biopsy)
   - Reducing the need for sparse healthcare resources such as medical geneticists
   - Informing parental reproductive decisions

   Typically, payers require pre- and post-testing genetics counseling, which should include a discussion of the risks and benefits of all the above. Just as it would be inappropriate for a genetics counselor not to include these points in a fully informed consent discussion, it's inappropriate for a payer to exclude them from a medical necessity consideration.
   In our opinion, if the information is relevant to the family and it would be included in the discussion with the genetics counselor and used as a defining coverage criterion. Notably, reproductive information would rarely if ever be the sole indication for genetic testing, so this argument is relevant primarily in establishing a broader definition of clinical utility.

4. Concern: Genomic studies are heterogeneous so there is no clear understanding of which patients would benefit.

   Illumina response: For multiple congenital anomalies, developmental delay and intellectual disabilities, there are 11 studies and 2 meta-analyses, including a 2023 study by Chung, reporting on these phenotypes as the primary population or as a separately reported population. Most, though not all, had prior genetic testing so diagnostic yields are generally lower for GS in these studies.

Study	Patient Population	N	Previous genetic testing	Design	Diagnostic Yield (DY)	Additional information
Lindstrand (2022)	Pediatric outpatients with neurodevelopmental disorders and intellectual disabilities	650	none	Randomized trial comparing GS first, GS second, CMA first	35% GS first 26% GS second 11% CMA first	Alternatives to WGS first delay dx by a year; 91% of neg. CMA first lost to follow-up
Stranneheim et al (2021)	Pediatric rare disease clinic (neuromuscular, epilepsy, immunology, intellectual disability, malformation syndromes, connective tissue disease, neurodevelopmental disorders)	3,219	NR	Outpatient Retrospective cohort study 84% proband only, 16% trio	40% (GS) overall 39% intellectual disability	Patients with intellectual disability and malformation syndromes typically had singleton analysis only
Lee et al (2020)	Pediatric neurological disorders (DD, epilepsy, neuro-muscular, movement disorders) Mean age 6 years	214	Patients had SOC testing including FISH, karyotyping, CMA, and single gene tests depending on indication	Outpatient Prospective cohort study	43.9% (GS)	Dx Yield by patient groups: Neuromuscular, 62.5% Epilepsy, 47.5% Developmental delay, 41.4% Movement disorders, 15.4% 23.4% immediate change of management
Turro et al (2020)	Pediatric and adult patients with developmental disorders	660	Not reported	Outpatient Prospective cohort	33% (GS)	The NDD cohort is one of 15 cohorts
Stavropoulos (2016)	Pediatric patients 89% with developmental delay	100	Minimal prior testing	Outpatient Paired design	34% (GS) 8% (CMA)	
Scocchia et al. (2019)	Indications for testing were congenital anomalies, DD, seizures, growth restriction and ID Median age 5 years	60	No prior testing 68%; no prior WES/WGS	Outpatient Prospective cohort	68.3% (GS)	48.8% change in management
Lindstrand et al (2019)	Patients referred for CMA analysis (primarily neurodevelopmental delay or syndromic NDD)	100	None	Outpatient Prospective cohort—paired study design	GS and CMS in all 100 patients 27 % (GS) 12% (CMA)	
Thiffault (2018)	Patients with suspected genetic disorders	80	Most patients (57/80; 71%) were tested with CMA or ES	Outpatient Retrospective	25% (GS) 22% (ES)	All but 2 diagnoses would have been made by WES (18/20)
Lionel (2017)	Children with suspected genetic condition (neurologic, musculo-skeletal, behavioral, cognitive, DD)	103	None	Outpatient Prospective cohort	41% (GS)* 24% (target NGS) 70 patients had both GS and ES 50% (GS) 37% (ES)	Results not reported separately

Bowling et al. (2017)	Genomic diagnosis for children with intellectual disability and/or developmental delay using WES and WGS as second line test	244 GS 127 ES	81% prior testing 60% CMA	Outpatient Retrospecti ve cohort	25% (GS) 27.5% in prior neg CMA	No difference ES and GS for indels and SNV. Expected given CMA done first.
Gilissen (2014)	Children with severe ID	50	Negative CMA and negative ES	Outpatient Prospective cohort	42% (GS)	
Clark (2018)	Meta-analysis of studies of children with suspected genetic diseases (including NICU & peds OP)	20,068	NA	Meta-analysis	41% (GS) 36% (ES) 10% (CMA)	GS and ES> than CMA*
Chung (2023)	Meta-analysis of studies of children with suspected genetic diseases (including NICU & peds OP)	50,417	variable	Meta-analysis	38% DY WES 34% DY WGS (p=NS) H2H: 1.2 higher odds Dx with WGS	Clinical utility higher for WGS (0.77) vs. (WGS 0.44)

5. Concern: WGS has not been clinically validated in the DD/ID/MCA population.

Illumina response: The Washington HTA covers whole exome sequencing for the same patient population as we request coverage for WGS. From the methodologist's perspective, there is not a need to "re-prove" that achieving diagnoses for patients with phenotypes suggestive of genetic disease will improve outcomes. There is clear evidence to support that WGS is more sensitive at detecting CNVs than CMA and more sensitive detecting CNV and SNV/in/dels than WES.

We view WGS as technological or laboratory enhancement that uses the same platform and the same chemistry to capture 99+% of the genome rather than 1% with WES. WGS is a clinically valid approach for establishing a diagnosis in a suspected genetic disorder.

The question is whether whole genome sequencing yields more actionable information resulting in change of management. In addition to assessing individual studies, meta-analyses can offer pertinent insights on both diagnostic yields and clinical utility.

The Clark (2018) meta-analysis included 37 studies and 20,068 probands. This study demonstrated 1) was the first demonstrating the diagnostic superiority of WES and WGS over CMA, 2) the diagnostic non-inferiority of WES and WGS, and 3) the clinical utility superiority of WGS over WES. This superiority consistently results in higher diagnostic yields with higher rates of change of management, consistent with your definition of clinical utility.

The recently published Chung (2023) meta-analysis compared the diagnostic and clinical utility of WES versus WGS in pediatric and adult patients with rare diseases using 161 studies and 50,417 probands. Diagnostic rates of WES (0.38, 95% CI 0.36-0.40) and WGS (0.34, 95% CI 0.30-0.38) were similar (p=0.1), and like Clark, likely reflect the impact of WES and WGS used as second- or third-line tests. Importantly, when evaluating within-cohort comparisons, the odds of making a diagnosis was 1.2 times higher for WGS vs. WES (95% CI 0.79-1.83, p=0.38). The rate of variants of unknown significance (VUS) did not differ (p=0.78). Like Clark, Chung found that among high-quality studies, clinical utility of WGS (0.77, 95% CI 0.64-0.90) was significantly higher than WES (0.44, 95% CI 0.30-0.58) (p<0.01).

6. Concern: CMA testing first will eliminate the need for more expensive testing.

Illumina's response: Multiple studies demonstrate that WGS as a first-line test is more clinically effective and cost-effective than alternative approaches, including CMA first.

Clinical effectiveness: Assuming a 10% diagnostic yield in patients with neurodevelopmental disorders and intellectual disability, 90% of patients would go on to have WES. From a clinical vantage point, this approach prolongs the diagnostic odyssey and increases the risk that patients will be lost to follow-up or not get guideline-indicated follow-up care. The following studies compare WGS to CMA.

- In a randomized controlled trial, Lindstrand evaluated the results of 3 different diagnostic approaches in patients with intellectual disability (ID) and/or neurodevelopment disorders (NDDs): genome sequencing (GS) first (N = 100), GS as a secondary test (N = 129), or chromosomal microarray (CMA) with or without FMR1 analysis (N = 421). The diagnostic yield was 35% (GS-first), 26% (GS as a secondary test), and 11% (CMA/FMR1). Notably, the age of diagnosis was delayed by 1 year when GS was performed as a secondary test and the cost per diagnosed individual was 36% lower with GS first than with CMA/FMR1. Furthermore, 91% of those with a negative result after CMA/FMR1 analysis (338 individuals) have not yet been referred for additional genetic testing and remain undiagnosed.
- Stavropoulos (2016) performed a prospective comparative study in which 100 patients with suspected genetic diseases received GS and CMA. GS identified genetic variants meeting clinical diagnostic criteria in 34% of cases, representing a fourfold increase in diagnostic rate over CMA (8%; P=0.00002), and identified all CNVs detected by CMA.
- Lindstrand 2019 reported that GS had an overall diagnostic rate of 27%, more than double compared to chromosomal microarray (12%) in a cohort of 100 patients with neurodevelopmental disorders/intellectual disability. The authors concluded that: "*These findings demonstrate that WGS may be used as a single test instead of performing two separate analyses to detect SVs and SNVs, such as CMA followed by WES, in addition to targeted analyses for specific repeat expansions and UPDs.*"

Cost-effectiveness: The economics clearly depend on the cost of each testing option as well as the diagnostic yield of CMA. Three economics studies are relevant.

- With specific reference to your question of CMA as a first-line test in the ID and DD populations, Runheim (2023) and colleagues studied the comparative healthcare costs and diagnostic yield using real-world data when WGS is performed as the first-line test instead of chromosomal microarray analysis (CMA). Two cohorts were analyzed retrospectively using register data, cohort CMA (418 patients) and cohort WGS (89 patients). The analysis compared diagnostic yield and healthcare consumption over a 2-year period after referral for genetic testing. The mean healthcare cost per patient in cohort WGS was $2,339 lower compared to cohort CMA (-$2339, 95% CI -$12,238 to -$7561; P = 0.64) including higher costs for genetic investigations ($1065, 95% CI $834-$1295; P < 0.001) and lower costs for outpatient care (-$2330, 95% CI -$3992 to -$669; P = 0.006). The diagnostic yield was 23% higher for cohort WGS (cohort CMA 20.1%, cohort WGS 24.7%) (0.046, 95% CI - 0.053-0.145; P = 0.36). The authors concluded WGS as a first-line diagnostic test for individuals with neurodevelopmental disorders is associated with statistically non-significant lower costs and higher diagnostic yield compared with CMA.

- Pertinent to the ID and DD populations, Li (2021) and colleagues published a cost effectiveness analysis of genome-wide sequencing for unexplained developmental disabilities and congenital anomalies. In this study, six strategies involving ES, GS, CMA, and other "standard" approaches

(e.g., single-gene tests, multi-gene panels) were compared to project the most cost-effective diagnostic approach. The results of the study demonstrated that all "genome-wide" approaches that comprehensively assessed all common variant types (i.e., CMA+ES, or GS) would be cost saving compared to either standard approaches or standard approaches followed by ES or GS. Based on the parameter inputs in their model, ES ($4589) plus CMA ($825) was less expensive than GS ($6235). Notably, using current benchmark pricing in the US from the Medicare Clinical Lab Fee Schedule, the cost of GS ($5031) is already less than the combination of ES ($4780) plus CMA ($1160), which would make GS the dominant strategy.

- In a study not specific to ID, DD or MCA, Lavelle (2022) at the Tufts Center for the Evaluation of Value and Risk in Health modelled the economic impact of GS as a first-line test in infants and children with suspected genetic conditions. In their study, first-line GS costs $15,048 per diagnosis vs. SOC for infants and $27,349 per diagnosis for children. If GS is unavailable, ES represents the next most efficient option compared with SOC ($15,543 per diagnosis for infants and $28,822 per diagnosis for children). Other strategies provided the same or fewer diagnoses at a higher incremental cost per diagnosis. The authors concluded that for all children, GS may be cost-effective under certain assumptions (i.e., disease severity, cost per standard of care diagnosis). Further, the authors concluded that if GS is unavailable, ES represents the next most efficient option.

  The above information would argue for allowing parity access to WGS and WES and in the DD/ID/MCA population, allowing access as a first-line test.

7. Concern: There is or little evidence on what subsequent tests should be done in exome negative patients. What is the utility of genomes after exomes? Should you repeat WES analysis, how frequently, and when should you do WGS after a negative WES.

   Illumina response: This is a short-term issue until genomes replace exomes and CMA as a first line test.

   There are studies that show a small incremental yield for CNV-related diagnoses for WGS following CMA. The table summarizes six studies of follow-up testing after prior negative WES and CMA testing. In general, with the addition of 100-150 new genetic diagnoses to OMIM annually, WES reanalysis ≥1 year later will establish diagnoses in a low percentage of children. For example, in the Ewans (2021)
   study, WES reanalysis after 2 years established a diagnosis in 7 of 38 (19%) of patients. Of the remaining undiagnosed patients, 6 of 31 (19%) has diagnoses established via WGS. Splinter (2018) found 8% diagnosis rate after WES analysis and an additional 6 (132) with WGS. Bertoli-Avella et al showed that up to 29.6% of ES negative cases could benefit from GS testing (14.5% with pathogenic or likely pathogenic results, and 15.1% with VUS).27 The majority of genetic diagnoses made by GS in ES negative cases could be attributed to its superior technical performance; GS detected 79 noncoding variants, 41 of which were classified as pathogenic/likely pathogenic.

Study	Patient Population	N	Previous genetic testing	Design	Diagnostic Yield (DY)	Additional information
Ewans et al (2022)	38 patients with suspected Mendelian disorders and a prior negative WES	38	Prior WES negative	Retrospective cohort study	34% (GS) including 18% (ES) dx'd by ES reanalysis	*DY ES re-analysis after 2 yrs = 18% (7/38) DY GS after neg. ES reanalysis = 19% (6/31)
Smedley et al (2021)	Pediatric and adult rare disease who had not been diagnosed after usual care in the UK NHS	2183	Due to eligibility criterion, most had standard genetic testing (e.g., single gene or panel-based)	Prospective cohort study	25% (GS) 14% *in silico* WES neg.	Ophthalmologic DY 44% Intellectual disability DY 40% Neurodev. D/O DY 29% 14% of diagnoses were found in regions not captured by WES 25% immediate change in management
Bertoli-Avella et al. (2020)	Complex, undiagnosed patients; broad spectrum of clinical presentations	1,007	36% (358) neg. ES 23% had "other" (karyotyping, Fragile X testing, MLPA analysis, methylation)	Retrospective cohort	21.1% (GS) 24.7% GS in never WGS	For ES neg. cases (358) , diagnostic yield for GS was 14.5% and 15.1% VUS On average, patients waited 5 years to receive a genetic diagnosis
Splinter et al. (2018)	Primary symptoms included neurologic, musculoskeletal, immunologic, gastrointestinal, rheumatologic)	132	Extensive testing prior to enrollment including single gene, CMA, ES, etc	Prospective cohort	24% (GS) (not all patients had GS) 35% overall (all methods)	13% (17/132) in patients with prior neg. WES 5% (6/132) in patients with prior neg. WES 8% (11/132) in patients with WES reanalysis
Sun et al (2022)	Pediatric patients with global developmental delay/intellectual disability	100	Prior negative ES and/or CMA	Prospective cohort	21% (GS) after ES reanalysis 7% (ES) reanalysis	
Thiffault et at (2018)	Patients with suspected genetic disorders (unbiased cohort based on normal ordering patterns) Average age 7.3 years	80	Most patients (57/80; 71%) were tested with CMA or ES	Retrospective	24% (GS)	All but 2 diagnoses would have been made by WES (18/20)

PLUGS policy Genomic Sequencing for Rare Disease (June 2022)

Re-analysis of previously obtained exome or genome sequence has the potential for additional diagnostic yield because of expanding variant databases, as well as periodic novel gene discovery and publication. Re-analysis could be considered prior to additional genomic sequencing, particularly if

- there has been onset or identification of additional symptoms that broadens the clinical phenotype assessed during the original ES/GS analysis, and/or
- there has been a change in the family history that expands the clinical picture, such as the birth or diagnosis of a similarly affected first-degree relative.

UHC policy Whole Exome and Whole Genome Sequencing

Reanalysis of WES after at least 18 months when above criteria for initial WES has been met and one of the following occurs:

- Individual experiences additional symptoms after initial WES that cannot be explained by the results of the initial WES; or
- New data or new family history emerges which suggest a link between the individual's symptoms and specific genes.

WGS is not Medically Necessary for any other clinical situation due to the availability of clinically equivalent diagnostic tests.

Cigna policy Whole Exome and Whole Genome Sequencing for Non-cancer Indications

"The differential diagnosis list and/or phenotype warrant testing of multiple genes and ONE of the following:

- Whole exome or whole genome sequencing is more practical than the separate single gene tests or panels that would be recommended based on the differential diagnosis.
- Whole exome or whole genome sequencing results may preclude the need for multiple and/or invasive procedures, follow-up, or screening that would be recommended in the absence of testing.

Whole Exome/Genome Reanalysis
Reanalysis of previously obtained uninformative whole exome or whole genome sequence data is considered medically necessary when the above criteria for whole exome/genome sequencing and ANY of the following conditions are met:

- onset of additional symptoms that broadens the phenotype assessed during the original exome/genome evaluation,
- birth or diagnosis of a similarly affected first-degree relative*** that has expanded the clinical picture,
- New scientific knowledge suggests a previously unknown link between the individual's findings and specific genes/pathogenic or likely pathogenic variants, AND
- at least 18 months have passed since the last analysis.

Policy recommendations: Given the uncertainty in this space, reanalysis using the Cigna criteria seems reasonable at least 1-2 years after negative ES or GS sequencing or prior reanalysis. WGS reanalysis seems reasonable using the same criteria and time intervals. There will likely remain uncertainty about the appropriate intervals. The ability of WGS to detect actionable mutations before and after WES and WES, however, is not in question.

Respectfully submitted,

John L. Fox, MD MHA
Senior Medical Director for the Americas
Market Access
[redacted]

[redacted]

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Cc: [redacted]
Subject: WGS comments- Labcorp
Date: Monday, June 26, 2023 2:20:16 PM
Attachments: image001.png
[redacted]

External Email

Attached are Labcorp's comments in regards to Whole Genome Sequencing coverage.

Please contact me if there are any issues or questions.

Thank you,

Jon Hassler
Sr. Policy and Payer Relations Analyst | Payer Relations
[redacted]
labcorp

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: 2023 HTA Prospective Technology Topics: Bariatric Surgery
Date: Monday, June 26, 2023 4:17:41 PM
Attachments: [redacted]

External Email

Dear Director Birch,

On behalf of Medtronic, I am submitting the attached comment letter regarding the rereview of bariatric surgery as one of the proposed technology topics.

Thank you,

Susan Hupp
Sr. Manager | Reimbursement and Payer Solutions
Medtronic
Medical Surgical Portfolio
[redacted]

Medtronic
Engineering the extraordinary

Medtronic

June 26, 2023

Via online submission at: shtap@hca.wa.gov

RE: WA State Health Care Authority, 2023 HTA Prospective Technology Topics: Bariatric Surgery

Dear Director Birch,

Medtronic, a leader in technologies and programs for obesity and metabolic surgery, is writing to provide support for the re-review of bariatric surgery. The depth of literature and guideline statements from specialty societies have shown bariatric surgery is associated with long-term weight loss and significantly reduces the incidence or progression of obesity-related comorbidities, as well as to improve quality of life.

We would like to support inclusion of the following aspects into the rereview of bariatric surgery:

- **Laparoscopic single anastomosis duodenal-ileal bypass with sleeve gastrectomy (SADI-S):** ASMBS expert panel has endorsed the procedure[1]. International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) has reviewed 50 studies and supports SADI-S[2]. Moreover, multiple commercial payers, including Aetna[3], BlueCross BlueShield of North Carolina[4], Cigna[5], Capital BlueCross[6], and Medica[7] include SADI-S as a medically necessary and covered procedure.

It is critical to have continued access to safe, effective, cost-effective, and durable treatment options for obesity like bariatric surgery. We hope the Washington State Health Care Authority will give due consideration to the evolving evidence on bariatric surgery.

Regards,

Susan Hupp

Susan Hupp
Sr. Manager, Health Economics Policy Reimbursement

[1] Kallies K, Rogers AM; American Society for Metabolic and Bariatric Surgery Clinical Issues Committee. American Society for Metabolic and Bariatric Surgery updated statement on single-anastomosis duodenal switch. Surg Obes Relat Dis. 2020 Jul;16(7):825-830. doi: 10.1016/j.soard.2020.03.020. Epub 2020 Mar 30. PMID: 32371036.

[2] Brown WA, Ooi G, Higa K, Himpens J, Torres A; IFSO-appointed task force reviewing the literature on SADI-S/OADS. Single Anastomosis Duodenal-Ileal Bypass with Sleeve Gastrectomy/One Anastomosis Duodenal Switch (SADI-S/OADS) IFSO Position Statement. Obes Surg. 2018 May;28(5):1207-1216. doi: 10.1007/s11695-018-3201-4. PMID: 29572769.

[3] https://www.aetna.com/cpb/medical/data/100_199/0157.html

[4] https://www.bluecrossnc.com/document/bariatric-surgery

[5]https://static.cigna.com/assets/chcp/pdf/coveragePolicies/medical/mm_0051_coveragepositioncriteria_bariatric_surgery.pdf

[6] https://www.capbluecross.com/wps/wcm/connect/prod_nws.capblue.com29556/d8845da0-15b8-4d03-8607-cb48249a1d3a/medical-policy-1-015.pdf?MOD=AJPERES&CVID=nydlOV5

[7] https://partner.medica.com/-/media/documents/provider/utilization-management-policies/iii-sur-30-um-policy.pdf?la=en&hash=4D0FF896B393D9996FB8C94428D11D7C

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: HTA Topic Proposal Feedback
Date: Monday, June 26, 2023 4:32:29 PM
Attachments: [redacted]

External Email

Hello,

Please see HTA topic proposal feedback letter attached.

Thank you,

Mei Li

Program Coordinator
Department of Laboratory Medicine and Pathology, University of Washington
[redacted]
Pronouns | She, Her

UW Medicine
LABORATORY MEDICINE
& PATHOLOGY

To Whom it May Concern:

We are encouraged that the Washington Health Technology Assessment program is considering a review of whole genome sequencing (WGS) in 2024 and are writing in support of this petition. There has been substantial evidence published evaluating WGS in patients with suspected genetic diseases demonstrating the clinical utility and positive impact on health outcomes of this technology. Over 750,000 Washingtonians have a rare disease and approximately 80% of rare diseases have a genetic cause. The diagnostic odyssey is defined as the time between when a symptom of a rare disease is first noted to the time when a final diagnosis is made. We know that the average diagnostic odyssey includes 8 specialists, takes 5-7 years, and costs $19K in diagnostic testing, with misdiagnoses along the way.

Within the Department of Laboratory Medicine and Pathology at the University of Washington, we serve multiple roles in overseeing the appropriate use of laboratory testing throughout our UW Medicine health system as well as in providing innovative and clinically useful laboratory testing such as genome sequencing. As testing options and the published literature have evolved, it has become increasingly clear that WGS should play an important role in establishing the correct diagnosis quickly in many patient populations for which a rare disease is a likely possibility. This is critical in ensuring that we prevent diagnostic errors and avoid diagnostic odysseys. However, this approach has not been broadly accepted for the conditions in which it can benefit patients.

Performing HTA review would be helpful in establishing the value for this testing and decreasing the uncertainty of its importance for multiple stakeholders. We strongly recommend that the Director select this topic for HTA review in 2024.

Sincerely,

Geoffrey S. Baird, MD, PhD
Professor and Chair
Paul E. Strandjord and Kathleen J. Clayson Endowed Chair
Department of Laboratory Medicine and Pathology

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: whole genome Medicaid coverage
Date: Monday, June 26, 2023 10:32:23 AM

External Email

To Whom it May Concern:

I am writing in support of the proposed HTA review of whole genome sequencing (WGS) for 2024. There has been substantial evidence published evaluating WGS in patients with suspected genetic diseases demonstrating the clinical utility and positive impact on health outcomes of this technology. Over 750,000 Washingtonians have a rare disease and approximately 80% of rare diseases have a genetic cause. We know that the average diagnostic odyssey for these patients includes 8 specialists, takes 5-7 years, and costs $19K in testing, with misdiagnoses along the way. Our organization is a member of PLUGS (schplugs.org), a not-for-profit national laboratory test stewardship network, which helps guides utilization of medically appropriate genetic tests. Genetic testing has historically followed a stepwise process, one test at a time, with hope that providers are able to select the best first test - which is time-consuming and costly, and many times doesn't provide an answer. Whole genome sequencing combines many tests into one and offers the best available diagnostic option for many individuals with undiagnosed rare disease. Think of it like upgrading to the newest smartphone technology and retiring the multiple devices you used before. Access to WGS in Washington ensures that the best tool can be used to end the diagnostic odyssey in specific circumstances.
We strongly recommend that the Director select this topic for HTA review in 2024.
Sincerely,

Kerry Lorenzo, MS, LGC

Genetic Counselor | Prenatal Diagnosis and Treatment Program | Pediatric Genetics
Seattle Children's Tri-Cities

[redacted]

[redacted]

[redacted]
www seattlechildrens.org/prenatal

intended recipient, please contact the sender by reply e-mail and destroy all copies of the original message.

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: Recommendation for whole genome sequencing for HTA review in 2024
Date: Monday, June 26, 2023 10:57:28 AM

External Email

To Whom it May Concern:

I am writing in support of the proposed HTA review of whole genome sequencing (WGS) for 2024.

There has been substantial evidence published evaluating WGS in patients with suspected genetic diseases demonstrating the clinical utility and positive impact on health outcomes of this technology. Over 750,000 Washingtonians have a rare disease and approximately 80% of rare diseases have a genetic cause. We know that the average diagnostic odyssey for these patients includes 8 specialists, takes 5-7 years, and costs $19K in testing, with misdiagnoses along the way.

Our organization is a member of PLUGS (schplugs.org), a not-for-profit national laboratory test stewardship network, which helps guides utilization of medically appropriate genetic tests. Genetic testing has historically followed a stepwise process, one test at a time, with hope that providers are able to select the best first test - which is time-consuming and costly, and many times doesn't provide an answer. Whole genome sequencing combines many tests into one and offers the best available diagnostic option for many individuals with undiagnosed rare disease. Think of it like upgrading to the newest smartphone technology and retiring the multiple devices you used before. Access to WGS in Washington ensures that the best tool can be used to end the diagnostic odyssey in specific circumstances.

We strongly recommend that the Director select this topic for HTA review in 2024.

Sincerely,
Jamie

Jamie Love-Nichols, MS, MPH, CGC
Pronouns: She/Her
Licensed, Certified Genetic Counselor
Genetic Counselor Supervisor
Genetic Medicine | Seattle Children's Hospital
[redacted]
-
[redacted]
www seattlechildrens.org

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Cc: [redacted]
Subject: Attention HTA: Letter of support for the evaluation of Whole Genome Sequencing
Date: Monday, June 26, 2023 12:52:53 PM
Attachments: [redacted]

External Email

Good afternoon,
Please find our attached letter of support for Whole Genome Sequencing to be evaluated by the HTA during the 2024 review cycle.

Sincerely,
Lauren

Lauren Lulis, MS, LCGC
Genetic Counselor
Genetic Test Utilization Program Manager

The CHOP Genetic Test Utilization Committee
The right test for the right patient at the right time
[redacted]

The GTUC was convened at the request of the Department of Pathology to review genetic testing orders in accordance with the relevant CHOP Genetic Testing Policy(s).
For forms and additional information: Genetic Test Utilization Committee

Children's Hospital of Philadelphia™

Children's Hospital of Philadelphia

Department of Pathology & Laboratory Medicine

June 26, 2023

Dear Director of the Washington Health Care Authority,

We are writing to support prioritization of the evaluation of whole genome sequencing (WGS) during the 2024 review cycle of the Health Technology Assessment (HTA) program. Genome sequencing (and more specifically rapid genome sequencing) has been shown to be a powerful diagnostic tool that is both effective and economical, with a track record in saving lives, limiting hospital stays and allowing better utilization of available resources for the sickest patients.

The genome refers to the entire collection of genetic material of an individual; it is composed of 3.2 billion letters of DNA which contain about 20,000 discrete genes. While previous technology allowed for analysis of 1-2% of the genome using various testing approaches (SNP microarray + mitochondrial sequencing + exome sequencing), advances have been made in the form of WGS that allows interrogation of the entire genome with extremely high throughput, resulting in more answers with a single test and a faster turnaround. Whole Genome Sequencing is a sophisticated genetic testing technology that is critical in providing diagnoses for individuals with complex medical conditions of unknown etiology and shortens the diagnostic odyssey. This faster route to diagnosis impacts clinical decision-making and reduces the psychological burden on the family [Cakici 2020, PMID: 33157008; Dimmock 2020, PMID: 33157007]. Furthermore, there is a positive economic net benefit to be realized through guiding the initiation of targeted therapies and interventions while simultaneously decreasing admission lengths and avoiding unnecessary procedures [Farnaes 2018, PMID: 29644095; Sanford 2022, PMID: 35141181]. Current genetic testing reimbursement practices limit access to diagnostic genetic testing for patients, which disproportionately negatively impacts patients from underserved populations. We support ensuring access to WGS for patients with severe disease regardless of race, ethnicity, or access to commercial insurance.

In summary, we urge you to pursue the evaluation of WGS as we are confident that approval of this technology will benefit the diverse patient population within Washington State (as well as other states).

Sincerely,

Lauren Lulis, MS, CGC, *Genetic Test Utilization Program Manager*

Jill Murrell, PhD, *Associate Professor; Co-Chair of Genetic Test Utilization Advisory Committee*

Colleen D. Campbell, MS, CGC, *Clinical Program Director – Genomic Diagnostics*

Nancy Spinner, PhD, *Chief, Division of Genomic Diagnostics*

Genetic Test Utilization Advisory Committee, The Children's Hospital of Philadelphia

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: Health technology assessment program Prospective technology topics – 2023
Date: Friday, June 23, 2023 6:43:02 AM
Attachments: [redacted]

External Email

Dear Ms. Birch,

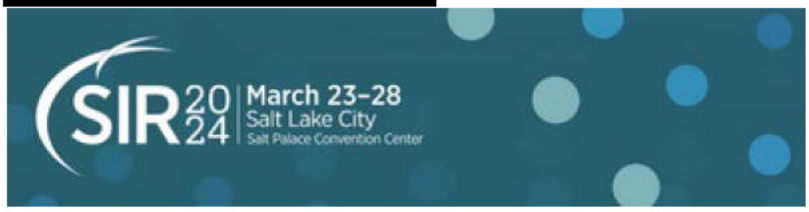
RE: Health technology assessment program Prospective technology topics – 2023; Rereview of vertebroplasty, kyphoplasty, and sacroplasty, as there may be the new evidence to change the original determination from 2011

The Society of Interventional Radiology (SIR) is a nonprofit, professional medical society representing the primary specialty of Interventional Radiology. Our 8,000 practicing interventional radiology physicians, trainees, students, scientists, and clinical associates are dedicated to improving patient care through image-guided therapy. Interventional radiologists diagnose and treat vertebral compression fractures using vertebroplasty, kyphoplasty, and sacroplasty procedures. Our letter provides new evidence for vertebroplasty, kyphoplasty, and sacroplasty procedures.

We appreciate you considering our comments. If you have any questions, please contact Ashley Maleki, Senior Manager of Health Policy and Economics at the Society of Interventional Radiology, at [redacted]

Kind Regards,

Ashley Maleki CPC, CPMA
Senior Manager, Health Policy and Economics
Society of Interventional Radiology
[redacted]



[redacted]

Society of Interventional Radiology
The vision to heal

sirweb.org

June 23, 2023

Sue Birch
Health Care Authority Director
Cherry Street Plaza
626 8th Avenue SE
Olympia, WA 98501
shtap@hca.wa.gov

RE: Health technology assessment program Prospective technology topics – 2023; Rereview of vertebroplasty, kyphoplasty, and sacroplasty, as there may be the new evidence to change the original determination from 2011

Dear Ms. Birch,

The Society of Interventional Radiology (SIR) is a nonprofit, professional medical society representing the primary specialty of Interventional Radiology. Our 8,000 practicing interventional radiology physicians, trainees, students, scientists, and clinical associates are dedicated to improving patient care through image-guided therapy. Interventional radiologists diagnose and treat vertebral compression fractures using vertebroplasty, kyphoplasty, and sacroplasty procedures.

Vertebral body and sacral fractures are a common cause of pain and disability, often associated with osteoporosis, cancer, and trauma. Vertebroplasty, kyphoplasty, and sacroplasty (vertebral augmentation) are minimally invasive procedures used to treat these fractures. The information below aims to present a comprehensive review of the most recent literature on their safety and efficacy, emphasizing their effectiveness in alleviating pain, improving functionality, and minimizing complications.

Efficacy of Vertebral augmentation:

a. A systematic review and meta-analysis by Zuo et al. (2018) evaluated 18 studies (n=1993) and reported significant pain reduction and functional improvement in patients undergoing vertebroplasty or kyphoplasty when compared to conservative therapy.[1]
b. A meta-analysis of more than 2 million patients by Hinde et al (2020), those with osteoporotic vertebral compression fractures who underwent vertebral augmentation were 22% less likely to die at up to 10 years after treatment than those who received nonsurgical treatment.[2]
c. A systematic review and meta-analysis by Chandra et al (2019) evaluated 19 studies (n=861) demonstrating significantly improved pain relief in patients with osteoporotic and malignant sacral fractures.[3]

Safety Profile:

a. A systematic review and meta-analysis by Chandra et al (2019) evaluated 19 studies (n=861) demonstrating a major complication rate of 0.3%.[3]

Cost-Effectiveness:

a. A systematic review by Pron et al (2022) evaluated 10 studies between 2008 and 2020 demonstrating cost-effectiveness of vertebroplasty and kyphoplasty compared to conservative management with earlier health gains and significantly shorter hospital stays. Ultimately vertebroplasty and kyphoplasty were demonstrated to be cost-effective in multiple healthcare settings.[4]

Access to these therapies today is broad, with WA state as one of the only coverage entities not considering the evidence sufficient for treatment. Medicare Administrative Contractors (MACs) recently updated their Local Coverage Determinations (LCDs) concerning coverage criteria for the treatment of VCFs in 2021. [4-12] All LCDs cover immediate access to vertebroplasty or kyphoplasty for patients that meet medical necessity criteria.[4-12] In the evidence summaries of these LCDs the MACs reference all prior randomized controlled trials (RCTs) and associated considerations that the WA HTA reviews have previously highlighted; but also review the breadth of evidence available inclusive of recent mortality data, guidelines, and a clinical care pathway created by a multispecialty expert panel.

We support the re-review of vertebroplasty, kyphoplasty, and sacroplasty. We respectfully request that the following bodies of evidence also be included in the next PICOS literature search criteria:

- Evidence related to mortality risk following surgical intervention relative to conservative medical management.[13-19]
- Considerations related to oral opioid reduction, as shown in a large retrospective real-world data analysis.[20]
- Care pathway recommendations developed by a multi-specialty physician panel, developed using the RAND/UCLA Appropriateness Method.[21]
- Evidence-based national guidelines, with three of the four recommending surgical treatment.[22-25]
- Additional cost-effectiveness data that was potentially missed in the last re-review due to exact timing of the publication.[26]

The most recent literature supports the safety and efficacy of vertebral augmentation in managing compression, pathologic, and insufficiency fractures. These procedures effectively alleviate pain and improve functionality, with low rates of major complications and adverse events. Additionally, they have been shown to be cost-effective compared to conservative management. Proper patient selection and procedural expertise remain crucial for optimal outcomes. These procedures are valuable treatment options for individuals suffering from vertebral and sacral fractures, backed by substantial evidence from recent studies.

We appreciate your consideration of our comments. If you have any questions, please contact Ashley Maleki, Senior Manager of Health Policy and Economics at the Society of Interventional Radiology, at [redacted]

Sincerely,

Alda L. Tam, MD, MBA, FSIR
President, Society of Interventional Radiology

cc:
Keith M. Hume, Executive Director, Society of Interventional Radiology

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References:

1. Zuo XH, Zhu XP, Bao HG, Xu CJ, Chen H, Gao XZ, Zhang QX. Network meta-analysis of percutaneous vertebroplasty, percutaneous kyphoplasty, nerve block, and conservative treatment for nonsurgery options of acute/subacute and chronic osteoporotic vertebral compression fractures (OVCFs) in short-term and long-term effects. Medicine (Baltimore). 2018 Jul;97(29):e11544. doi: 10.1097/MD.0000000000011544. PMID: 30024546; PMCID: PMC6086478.
2. Mortality Outcomes of Vertebral Augmentation (Vertebroplasty and/or Balloon Kyphoplasty) for Osteoporotic Vertebral Compression Fractures: A Systematic Review and Meta-Analysis Kenji Hinde, Julian Maingard, Joshua A. Hirsch, Kevin Phan, Hamed Asadi, and Ronil V. Chandra Radiology 2020 295:1, 96-103
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From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: Support for WA HTA Review of WGS
Date: Monday, June 26, 2023 10:21:00 AM

External Email

To Whom it May Concern:
I am writing in support of the proposed HTA review of whole genome sequencing (WGS) for 2024.

There has been substantial evidence published evaluating WGS in patients with suspected genetic diseases demonstrating the clinical utility and positive impact on health outcomes of this technology. Over 750,000 Washingtonians have a rare disease and approximately 80% of rare diseases have a genetic cause. We know that the average diagnostic odyssey for these patients includes 8 specialists, takes 5-7 years, and costs $19K in testing, with misdiagnoses along the way.

Our organization is a member of PLUGS (schplugs.org), a not-for-profit national laboratory test stewardship network, which helps guides utilization of medically appropriate genetic tests. Genetic testing has historically followed a stepwise process, one test at a time, with hope that providers are able to select the best first test - which is time-consuming and costly, and many times doesn't provide an answer. Whole genome sequencing combines many tests into one and offers the best available diagnostic option for many individuals with undiagnosed rare disease. Think of it like upgrading to the newest smartphone technology and retiring the multiple devices you used before. Access to WGS in Washington ensures that the best tool can be used to end the diagnostic odyssey in specific circumstances.

We strongly recommend that the Director select this topic for HTA review in 2024.

Sincerely,

Maria Mills, MS, CGC
Genetic Counselor | Craniofacial Medicine & Biochemical Genetics
Seattle Children's Hospital
Pronouns: she/hers
[redacted]

Hamann, Valerie (HCA)

From: [redacted]
Sent: Tuesday, June 13, 2023 10:27 AM
To: HCA ST Health Tech Assessment Prog
Subject: Treatments for chondral defects of the knee

External Email

HTCC Public Comment:

OATS ankle surgery was previously reviewed by the HTCC and denied because the diluted experience of the committee members lead to recorded comments within the deliberation minutes that the non-Orthopedic Surgeons didn't know enough about the procedure and therefore couldn't take a position, so therefore declined to recommend (terrible logic that is contrary to the intended purpose of putting an Orthopedic Surgeon on the committee to help inform the reset of the members), and anyone that might be aggrieved could simply appeal. Only, the law in place at the time was established by *Joy v. Dep't of Labor & Industries* and said that nobody could effectively appeal an HTCC position. At the time I represented a gentleman who needed OATS ankle surgery and benefited greatly from it. His pre-surgical choices were effectively reduced to becoming a lifelong cripple with a fused ankle that would then disrupt biomechanical processes in all collateral weight-bearing joints, or go through with the OATS procedure despite the fact that it wasn't HTCC-approved. That case (James Lewis) got stayed in the Court of Appeals and thereafter remanded for authorization of the OATS ankle surgery within 60 days of when the Supreme Court reversed *Joy*.

The committee members need to understand that these decisions of the HTCC have real-world consequences. In my client's case, the Department of Labor & Industries ALSO denied my client time loss payments in the post-surgical period, reasoning that if the surgery wasn't authorized, the consequential need to be out of work was also not going to be compensated. It didn't matter to the Department that my client couldn't work under any circumstances anyway because he had a massive osteochondral defect that made it too painful to walk without having the procedure.

At the time of the OATS ankle procedure review, an invited Orthopedic Surgeon gave testimony to the HTCC that the procedure is used successfully and safely in knees and with better results than alternative procedures like fusion. Nobody on the committee would agree to have a knee fusion if they could instead replace an articular cartilage defect and thereafter resume normal activities, right? Here, we shouldn't deny this procedure to injured workers or others, especially given the historic testimony considered by the HTCC previously, as well as the massive collateral consequences HTCC determinations can have on the rights of this state's most vulnerable populations.

Respectfully, everyone needs to listen to the Orthopedic Surgeon on the committee. This procedure is safe, predictable, and leads to better results, which was a research determination discussed in the meeting minutes while OATS ankle surgery was being previously rejected by a dysfunctional committee. Please do not allow the composition of the committee to dilute the relevant expertise that exists on the panel. In this case, give the weight of the consideration to the Orthopedic Surgeon, since that's the credentialing most competent in informing the committee's analysis.

Please approve these procedures so that my injured workers that I represent can have faster access to high-quality medical care consistent with the statutory mandate at RCW 51.36.010.

Thank you,

Spencer Parr
Attorney - Partner

[redacted]

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: Support for WA HTA Review of WGS
Date: Monday, June 26, 2023 11:41:42 AM

External Email

To Whom it May Concern,

I am writing in support of the proposed HTA review of whole genome sequencing (WGS) for 2024.

There has been substantial evidence published evaluating WGS in patients with suspected genetic diseases demonstrating the clinical utility and positive impact on health outcomes of this technology. Over 750,000 Washingtonians have a rare disease and approximately 80% of rare diseases have a genetic cause. We know that the average diagnostic odyssey for these patients includes 8 specialists, takes 5-7 years, and costs $19K in testing, with misdiagnoses along the way.

Our organization is a member of PLUGS (schplugs.org), a not-for-profit national laboratory test stewardship network, which helps guides utilization of medically appropriate genetic tests. Genetic testing has historically followed a stepwise process, one test at a time, with hope that providers are able to select the best first test - which is time-consuming and costly, and many times doesn't provide an answer. Whole genome sequencing combines many tests into one and offers the best available diagnostic option for many individuals with undiagnosed rare disease. Think of it like upgrading to the newest smartphone technology and retiring the multiple devices you used before. Access to WGS in Washington ensures that the best tool can be used to end the diagnostic odyssey in specific circumstances.

We strongly recommend that the Director select this topic for HTA review in 2024.

Sincerely,

Abbey Scott

Abbey Scott, MS, CGC (she/her)
Inpatient Genetic Counselor III
Seattle Children's Hospital
[redacted]

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: Support for WA HTA Review of WGS
Date: Monday, June 26, 2023 3:14:37 PM
Attachments: [redacted]

External Email

To Whom it May Concern:
I am writing in support of the proposed HTA review of whole genome sequencing (WGS) for 2024. I know many children and families that would be positively impacted by this advance.

There has been substantial evidence published evaluating WGS in patients with suspected genetic diseases demonstrating the clinical utility and positive impact on health outcomes of this technology. Over 750,000 Washingtonians have a rare disease and approximately 80% of rare diseases have a genetic cause. We know that the average diagnostic odyssey for these patients includes 8 specialists, takes 5-7 years, and costs $19K in testing, with misdiagnoses along the way.

Our organization is a member of PLUGS (schplugs.org), a not-for-profit national laboratory test stewardship network, which helps guides utilization of medically appropriate genetic tests. Genetic testing has historically followed a stepwise process, one test at a time, with hope that providers are able to select the best first test - which is time-consuming and costly, and many times doesn't provide an answer. Whole genome sequencing combines many tests into one and offers the best available diagnostic option for many individuals with undiagnosed rare disease. Think of it like upgrading to the newest smartphone technology and retiring the multiple devices you used before. Access to WGS in Washington ensures that the best tool can be used to end the diagnostic odyssey in specific circumstances.

We strongly recommend that the Director select this topic for HTA review in 2024.

Sincerely,

Kiana Siefkas, MS, LGC
Lead Genetic Counselor | Prenatal Diagnosis and Treatment Program
Seattle Children's
[redacted]
www seattlechildrens.org/prenatal

Connect with us online:

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Cc: Paul Kruszka
Subject: Comments for proposed topic: whole genome sequencing
Date: Monday, June 26, 2023 1:22:05 PM
Attachments: [redacted]

External Email

Please see attached comments for topic proposal of whole genome sequencing. Let us know if you have any questions.

Thank you.

Sarah Soto, MS CGC
Medical Policy Impact and Payer Evidence Strategy
Market Access
GeneDx | GeneDx.com

[redacted]

June 26, 2023

Washington State Health Care Authority,

Thank you for the opportunity to provide public comment. Specifically, I would like to address the need for Washington State to provide patient access to Genome Sequencing (GS) which has important considerations related to your primary criteria for selecting a topic (efficacy, safety, and cost). Thank you for providing this important opportunity, as this valuable technology has the potential to end the diagnostic odyssey for many of Washington's most vulnerable.

I am a board-certified clinical geneticist and have advocated for undiagnosed patients during the last two decades. My comments revolve around the importance of reviewing GS for the purpose of aligning Washingtons' policy with existing evidence-based professional society guidelines. Most rare diseases are serious genetic conditions associated with substantial morbidity and mortality that collectively impact 25 to 30 million people in the United States. These conditions can be challenging to diagnose, often with years-long invasive and costly diagnostic odysseys including the involvement of numerous specialists ordering serial genetic testing and costly medical interventions. Over the past decade, exome sequencing (ES) and now GS has increasingly been used as a single genetic test providing a timely diagnosis to inform appropriate care.

There have been extensive publications related to the efficacy of GS including a systematic evidence review with meta-analysis and subsequent evidence-based guideline by the American College of Genetics and Genomics (ACMG) strongly recommending GS as a first-tier test (Manickam et al., 2021). Furthermore, GS has a diagnostic rate two to three times higher than traditional genetic testing including chromosomal microarray, single gene and targeted panel testing which have broad payer coverage with widespread use (Clark et al., 2018; Health Quality Ontario, 2020; Incerti et al., 2022). The diagnostic yield of GS is greater than 30%, reported by a systematic review and meta-analysis with clinical utility studies including a meta-analysis have demonstrated that up to ~ 60% of patients with a positive GS result have a change in medical management (Incerti et al., 2022; Chung et al., 2023). These modifications included change in medication (new treatment or halting an existing one), alteration to diet, change in planned procedures or surveillance (surgery, imaging, and/or diagnostic studies), referral to specialist, testing of family members, and/or impact on future reproductive planning (Manickam et al., 2021). Some national payers as well as organizations that provide guidance policies for payers cover GS.

Cost is an important consideration as the standard diagnostic work-up for patients with suspected rare genetic disorders is typically a time-consuming and expensive process (Tan et al., 2017). Numerous health economic studies have also been published on GS with a recent cost-effectiveness analysis from a United States health sector perspective demonstrating that GS has a higher detection rate and shortens the diagnostic odyssey, but at a similar cost compared to standard care for children with suspected rare genetic diseases (Incerti et al., 2022). An evidence-based guideline by ACMG stated "… *GS has a higher diagnostic yield and may be more cost-effective when ordered early in the diagnostic evaluation*" (Manickam et al., 2021).

Safety and harms are also an important consideration for GS similar to the considerations in the Washington State Health Care Authority's report for Whole Exome Sequencing. Evidence-based practice guidelines by ACMG and National Society of Genetic Counselors (NSGC) have assessed the balance of effects of GS. The ACMG systematic evidence review identified minimal evidence of harm associated with GS and concluded that the findings across multiple clinical settings suggest no clinically significant psychological harms from the return of genomic sequencing results, and that there may be greater positive psychological effects associated with GS (Manickam et al., 2021). Additionally, the NSGC guideline supports the expansion of access to genetic testing but acknowledge insurance reimbursement remains a barrier" (Smith et al., 2022). This guideline has been endorsed by the American Epilepsy Society.

Patient-centered Laboratory Utilization Guidance Services (PLUGS) is a laboratory stewardship collaborative based at Seattle Children's Hospital and provides sample policies to guide coverage and reimbursement for medically appropriate genetic tests (PLUGS, 2023c). PLUGS policy on "Genomic Sequencing for Rare Disease" covers GS in several clinical scenarios (PLUGS, 2023b) and "Epilepsy Genetic Testing Policy" covers GS for patients with epilepsy of unexplained etiology with onset at any age stating, "*Genome sequencing is the most effective first-line test for diagnosing genetic epilepsy*" (PLUGS, 2023a).

To best serve the children and families of Washington State impacted by rare genetic disease, I am asking the Washington State Health Technology Assessment (HTA) program to review genome sequencing (GS):

- GS is intended for individuals with a suspected rare genetic disorder in which the clinical findings may include congenital anomalies, neurodevelopmental disorders (e.g., epilepsy, developmental delay, intellectual disability, autism spectrum disorders, developmental regression), or dysmorphic features (Clark et al., 2018).

- GS should be ordered by an appropriate healthcare provider (medical geneticist, genetic counselor, neurologist, neonatologist, developmental pediatrician, or other qualified clinician) (Bowdin et al., 2016; Savatt & Myers, 2021).

GS meets the Washington State Health Care Authority's topic selection criteria as it has important considerations related efficacy, safety, and cost. Washington State is fortunate to have a robust community of genetics practitioners whose professional societies have laid out evidence-based guidelines for the use of GS. To best serve diagnostic odyssey patients in the State of Washington, I would ask that you consider this technology review as a priority topic for the upcoming review cycle.

Thank you for your consideration,

Paul Kruszka MD, FACMG
Chief Medical Officer
GeneDx

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Hamann, Valerie (HCA)

From: Wellner, Monica [redacted]
Sent: Thursday, June 22, 2023 9:43 AM
To: HCA ST Health Tech Assessment Prog
Subject: HTA Program Review Topic Selection - WGS

Importance: High

External Email

To Whom it May Concern:

I am writing on behalf of the PLUGS network in support of the proposed HTA review of whole genome sequencing (WGS) for 2024. We lead a not-for-profit national laboratory test stewardship network called PLUGS (Patient-centered Laboratory Utilization Guidance Services), which helps guide utilization of medically appropriate genetic tests and focuses on insurance collaboration, including in our home state of WA. Genetic testing has historically followed a stepwise process, one test at a time, with hope that providers are able to select the best first test - which is time-consuming and costly, and many times doesn't provide an answer. Whole genome sequencing combines many tests into one and offers the best available diagnostic option for many individuals with undiagnosed rare disease. Think of it like upgrading to the newest smartphone technology and retiring the multiple devices you used before. Access to WGS in Washington ensures that the best tool can be used to end the diagnostic odyssey in specific circumstances. In the past, we worked closely with the Committee on the review of exome sequencing coverage and collaborated with Dr. Shana Johnson to develop meaningful coverage criteria for patients to access this test, using the PLUGS consensus policies as a guide. We are eager to see this topic discussed in 2024 and available to provide our expertise during the discussion.

We strongly recommend that the Director select this topic for HTA review in 2024.

Sincerely,

Monica Wellner

Monica Wellner
Laboratory Director, Specialty Laboratories and Programs
Director of Operations | PLUGS
Seattle Children's
[redacted]

Seattle Children's® HOSPITAL • RESEARCH • FOUNDATION | PLUGS® Patient-centered Laboratory Utilization Guidance Services

From: [redacted]
To: HCA ST Health Tech Assessment Prog
Subject: Support for WA HTA Review of WGS
Date: Monday, June 26, 2023 11:34:53 AM

External Email

To Whom it May Concern,

My name is Megan Yabumoto and I am a pediatric genetic counselor at Seattle Children's Hospital. I have been practicing as a genetic counselor for a year now and have directly witnessed the impact a known genetic diagnosis has on patients, their family members, and their care team. I am writing in support of the proposed HTA review of whole genome sequencing (WGS) for 2024.

There has been substantial evidence published evaluating WGS in patients with suspected genetic diseases demonstrating the clinical utility and positive impact on health outcomes of this technology. Over 750,000 Washingtonians have a rare disease and approximately 80% of rare diseases have a genetic cause. We know that the average diagnostic odyssey for these patients includes 8 specialists, takes 5-7 years, and costs $19K in testing, with misdiagnoses along the way.

Our organization is a member of PLUGS (schplugs.org), a not-for-profit national laboratory test stewardship network, which helps guides utilization of medically appropriate genetic tests. Genetic testing has historically followed a stepwise process, one test at a time, with hope that providers are able to select the best first test - which is time-consuming and costly, and many times doesn't provide an answer. Whole genome sequencing combines many tests into one and offers the best available diagnostic option for many individuals with undiagnosed rare disease. Think of it like upgrading to the newest smartphone technology and retiring the multiple devices you used before. Access to WGS in Washington ensures that the best tool can be used to end the diagnostic odyssey in specific circumstances.

We strongly recommend that the Director select this topic for HTA review in 2024.

Sincerely,

Megan Yabumoto, MS, CGC

Megan Yabumoto, MS, CGC (she/her)
Licensed, Certified Genetic Counselor | Medical Genetics
Seattle Children's Hospital
[redacted]
WWW seattlechildrens.org