

Insurance and Reimbursement Process for the *SImmetry*[®] Device



Rebecca M. Villandry, RN, BSN Manager, Clinical Specialist Team



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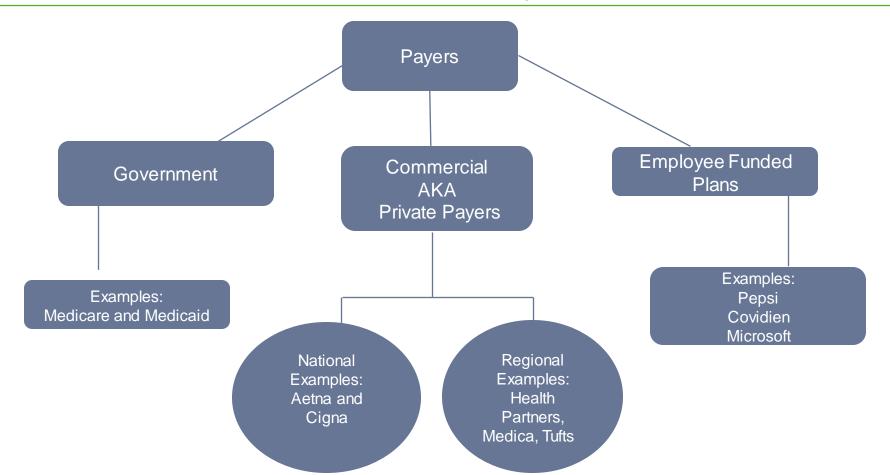




- Payer Landscape
- Prior Authorization and Appeals Process
- Reimbursement and Coverage Access Resources
- Coverage Snapshot
- Summary

Who are the Payers?

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Hints and Helps



Commercial Payers:

- Each payer/policy is different
- Prior authorization is required for most plans
- Many payers consider SI joint fusion as investigational and experimental
- Appeal process can be lengthy (statutory rules for timeframes)

Medicare, Medicaid:

- Medicare: **NO** prior authorization required for Part A/B
- Med-Advantage Plans: require prior authorization (same as commercial)
- Medicaid policies: differ at state/local levels

Medicare



- Federal Health Insurance program for people over 65 years of age
- Over 60 million beneficiaries¹
- National Offices in Baltimore, Maryland
- Most coverage determinations are made locally

Medicaid



- Government plan that provides healthcare for low income individuals that have no other way to pay
 - "Indigent" population
- State controls the hands-on operation
- Regulations and coverage determinations vary from state to state¹
- Typically low paying
- Prior-authorization is encouraged for Medicaid patients

Employer Funded Plans



- Cost effective for a large employer due to prohibitive cost of premiums
- Employer can override the insurance provider's coverage criteria
- SI joint fusion appeals to employers
 - Contain costs for medical services
 - Employers familiar with high cost of lumbar fusion
 - Goal of human resources is to keep employees satisfied and productive

SI Joint Fusion as Treatment



- Surgeon prescribes SI joint fusion for the patient
- Insurance coverage identified
- Office staff verifies patient benefits and the process to obtain insurance approval initiated
- Coordination between surgeon, staff, and patient

Your Clinical Specialist Team is here to provide coverage access support!

Prior Authorization Process



- Surgeon prescribes treatment with the *SImmetry* system
- Prior authorization personnel completes benefits verification
- Outpatient procedures appear not to require prior authorization, but for the *SImmetry* system, they actually do!
 - Request will be assigned to a payer review nurse
 - Review nurse determines if clinical documentation meets coverage policy or clinical practice guidelines; is it on-label?
 - Review Nurse has authority to approve case
 - Prior authorization process is typically completed within 2 weeks
- If the clinical documentation does not meet guideline requirements, the request is forwarded to a Medical Director for review

Required Documentation and Prior Authorization ^{rtj surgical}

Surgeon must **establish medical necessity** for procedure and implant for the specific patient. The prior authorization process may require submitting some or all of the following documentation:

- Reference NASS¹ and ISASS² guidelines most coverage policies are tied to these guidelines
- Clinical notes
- Diagnostic tests
 - Provocative tests
 - Diagnostic injections
- Imaging
 - Recent, needs to align with diagnosis and rule out other pathology
- Conservative treatment failure must use dates (e.g. March 2016-January 2018)

 North American Spine Society (NASS). NASS Coverage Policy Recommendations. Percutaneous Sacroiliac Joint Fusion. June 2015. Available at: <u>https://www.spine.org/PolicyPractice/CoverageRecommendations/CoverageRecommendations</u>
 Lorio MP, Rashbaum R. ISASS Policy 2016 Update - Minimally Invasive Sacroiliac Joint Fusion. Int J Spine Surg. 2016; p.4. <u>https://www.isass.org/isass-policy-statement-minimally-invasive-sacroiliac-joint-fusion-july-2016/</u>

Aetna's Coverage Policy¹ - Sacroiliac joint fusion

Minimally invasive arthrodesis of the sacroiliac joint (e.g., iFuse) is considered medically necessary for sacroiliac joint syndrome interfering with activities of daily living when all of the following criteria are met:

- Adults 18 years of age or older with sacroiliac joint (SIJ) pain for greater than 6 months (or greater than 18 months for pregnancy induced pelvic girdle pain): and
- Diagnosis of the SI joint as the primary pain generator based on all of the following:
 - Member has pain at or close to the posterior superior iliac spine (PSIS) with possible radiation into buttocks, posterior thigh or groin and can point to the location of pain (Fortin Finger Test); and
 - Member has at least 3 of 5 physical examination maneuvers specific for SI joint pain:
 - Other causes of low back pain have been ruled out, including lumbar disc degeneration, lumbar disc herniation, lumbar spondyl olisthesis, lumbar spinal stenosis, lumbar facet degeneration, and lumbar vertebral body fracture;
 - Clinician has documented that other neighboring motion segments have been evaluated and ruled out as potential pain generators, including diagnostic testing with facet/medial branch blocks and or interlaminar epidural injections, as appropriate based on the member's presentation; and

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- D Member has had recent (within 6 months) diagnostic imaging studies that include all of the following:
 - Plain X-rays and/or cross sectional imaging (CT or MRI) that excludes the presence of destructive lesions (e.g. tumor, infection), acute fracture or inflammatory arthropathy that would not be properly addressed by SIJ fusion; and
 - Plain X-rays of the pelvis including the ipsilateral hip to evaluate potential concomitant hip pathology; and
 - Cross-sectional imaging (e.g. CT or MRI) of the lumbar spine to evaluate potential concomitant neural compression or other degenerative conditions; and
- Sacroiliac pathology is not caused by autoimmune disease (e.g. ankylosing spondylitis) and/or neoplasia (e.g. benign or malig nant tumor) and/or crystal arthropathy; and
 Member has improvement in lower back pain numeric rating scale (NRS) of at least 70% of the pre injection NRS score after two separate fluoroscopic or CT controlled injection of local anesthetic into affected SI joint; and
- Baseline lower back pain score of at least 5 on 0-10 point NRS; and
- Member should have tried 6 months of adequate forms of conservative treatment with little or no response, including pharmacotherapy (e.g., NSAIDS), activity modification, and active therapy (including 3 or more months of physical therapy).

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Supporting clinical and technical information

- 510(k) clearance letter
- Peer-reviewed clinical literature
- NASS¹ and ISASS² society recommendations for treatment and coverage
- Description of the technology

 North American Spine Society (NASS). NASS Coverage Policy Recommendations. Percutaneous Sacroiliac Joint Fusion. June 2015. Available at: https://www.spine.org/PolicyPractice/CoverageRecommendations/CoverageRecommendations
 Lorio MP, Rashbaum R. ISASS Policy 2016 Update - Minimally Invasive Sacroiliac Joint Fusion. Int J Spine Surg. 2016; p.4. https://www.isass.org/isass-policy-statement-minimally-invasive-sacroiliac-joint-fusion-july-2016/

If Prior Authorization is Denied... Appeal Process ^{rti surgical}

Initiate Prior Authorization (1–15 Days)

- Verify benefits and submit clinical information and literature.
- Peer-to-Peer (1–3 Days)
- Opportunity for the treating physician to discuss the medical necessity of the case with a Medical Director at the health plan.

If Prior Authorization is Denied:

- 1st Level Appeal (3–30 Days)
 - Expedited/Standard Opportunity to request a Medical Director that did not review the initial submission. There may be one or two levels of internal appeals.
- 2nd Level Appeal (3–30 Days)
 - Expedited/Standard Opportunity to request a Medical Director that did not review the initial submission as well as the peer to peer.
- External Appeal (5–45 Days)
 - Following appeal denial at all available internal levels, the patient should pursue an External Appeal with the applicable State Department of Insurance.

Reimbursement and Coverage Access Resources rti surgical

SImmetry **Coding Card** Current as of January 1st, 2020

SIMMETRY REIMBURSEMENT HOTLINE

866-325-4031 | reimbursement@rtix.com

SURGEON CODING AND PAYMENT OPTIONS

Arthrodesis, sacrolliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device.

CPT^{®1} Code: 27279 | For bilateral procedure: report 27279 with modifier 50

1. 2020 Current Procedural Terminology (CPT®) Professional Edition. CPT is a registered trademark of the American Medical Association. All rights reserved. 2 CMS-1715F: Medicare Physician Fee Schedule Final Rule CY2O2D Effective through December 31 2020 Conversion factor \$360896 *Final Medicare payment will vary based on physician boality adjustments. Commercial payment will be determined by individually regotiated contracts.

Medicare National Average Payment² \$914.51

NOTE: Final coding for minimally investive sacrolliac joint fusion procedures is at the discretion of the healthcare provider and the directive of the payer. Providers are encouraged to contact their payer with questions pertaining to coding, coverage or claims submission for this procedure.

HOSPITAL INPATIENT/ OUTPATIENT PROCEDURE CODING AND REIMBURSEMENT

Hospital Inpatient Procedure Coding and Payment

Percutaneous sacroiliac ioint fusion with internal fixation device, right side ICD-10 Procedure Code1: 0SG734Z Percutaneous sacroiliac ioint fusion with internal fixation device. left side ICD-10 Procedure Code¹: 0SG834Z

DRG Assignment and Medicare National Average Payment² DRG 460 Spinal fusion, except cervical \$24,787,99

Final payment will vary by individual hospital. Commercial insurance payment will be determined by individually negotiated contracts. NOTE: Final DRG placement will be determined by procedures performed, level of severity of patient's overall health-related conditions and pre-existing comorbidities.

Hospital Outpatient Procedure Coding and Payment

Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device.

CPT®3 Code: 27279 | Status Indicator4 J1 APC Assignment and Medicare National Average Payment⁴ 5116 Level VI Musculoskeletal Procedures | \$15.946.08

1. 2020 ICD Procedure Coding System (ICD-10-PCS) Expert for Hospitals, AAPC.

Simmetry System Device Category Anchor/Screw for opposing bone-to-bone or soft tissue-to-bone (implantable)

HCPCS Code5: C1713

Medicare National Average Payment⁴

Status N1⁵ | No Separate Payment Packaged into Payment for Procedure

2. CMS-1716F. CMS-1716 CN2; Medicare Hospital Inpatient Prospective Parment Systems for Acute Care Hospital and Long-Term Care Hospital Prospective Payment System and Policy Chances and Fiscal Year 2020 Rates. Effective through September 30, 2020. 3. 2020 Current Procedural Terminology (CPT®) Professional Edition, CPT is a registered trademark of the American Medical Association, All rights reserved.

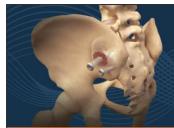
- 4. CMS-1717-CN: Medicare Outpatient Payment System Final Rule CY2020. Effective through December 31, 2020.
- 5. 2020 Healthcare Common Procedure Coding System (HCPCS) Level II Expert. AAPC.

*2020 Medicare national average payment, Final Medicare payment will vary based on locality adjustments, Commercial payment will be determined by individually negotiated contracts.

It is the responsibility of the healthcare provider to determine the best treatment for each patient based on each patient's condition and diagnosis. The codes denoted within are suggestions only. This information should not be construed as authoritative. Codes and values billing and odding requirements ascribed by pages with whom they werk. When making odding deckines, we knowcape you to seek (upper from the AMA), relevant medical oddings, OAS, you local Medicare Administrative Confector and other health plans to which you submit clears. All we have have no work of the advector of the seak of the section. All data relevant herein at based on publicity valiable information.

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Simmetry Coding Card Current as of January 1st, 2020



ASC CODING/REIMBURSEMENT

Procedure Coding and Payment

Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device.

CPT®1 Code: 27279

Medicare National Average Payment²: \$12,982.29

INTENDED USE/INDICATION FOR USE:

The Simmetry Sacroiliac Joint Fusion System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

Learn more at rtix.com/en_us/products/product-implant/ simmetry-si-joint-fusion-system

Simmetry System Device Category

Anchor/Screw for opposing bone-to-bone or soft tissue-to-bone (implantable)

SIM

HCPCS Code3: C1713

Medicare National Average Payment² Status N1 | No Separate Payment Packaged Into Payment for Procedure

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2 CMS-1716F, CMS-1716-CN2, Medicare Hospital Inpatent Propertile Payment Systems for Acute Care Hospital and Long-Term Care Hospital Propertile Payment System and Policy Changes and Rocal Year 2020 Rates. Effective through September 30, 2020. 3. 2020 Current Procedural Terminology (CPT*) Professional Edition. CPT* is a registered trademark of the American Medical Association. All rights reserved.

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NOTE: Final coding for minimally invasive sacrolliac joint fusion procedures is at the discretion of the healthcare provider and the directive of the payer. Providers are encouraged to contact their payer with questions pertaining to coding, coverage or claims submission for this procedure.



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See product insert for complete labeling limitation related to this device, 510(K) FDA approval in 2011, K102907, Regulation number 210FR888.304 The Simmetry device is manufactured for affiliates of RTI Surgical Holdings, Inc. Distributed by: RTI Surgical, Inc. 11621 Research Circle Alachua, Florida 32615 t: 877.343.6832 www.rtisurgical.com

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Reimbursement and Coverage Access Resources

- 2020 Coding Card ٠
- Pre-authorization Checklist
- SI Diagnostic Worksheet



Pre-authorization Checklist for SI Fusion Approval

If you are doing pre-authorization for SI fusions, below are recommended steps for approval. All must be submitted at the same time.

1. Patient History

· Trauma, Minor Trauma Prior Lumbar Surgery

· Chronic Pain (include date of when pain started) Pregnancy / Post-Partum

· Climbing stairs

· Riding in the car

Standing for long periods

2. Physical Exam

· Tendemess to palpation over the SI sulcus Positive Fortin Finger Test

3. Patient Experiences Symptoms When:

· Sitting or sleeping on painful side · Walking (gait) · Standing on one leg · Sitting to standing

4. Provacative Test Results

Distraction	 Compression 		
Thigh-Thrust	FABER		
Gaenslen	Yeoman's		

5. Diagnostic injection results showing pain reduction and abnormalities in the SI joint

- 6. Updated MRI within 6 months
- 7. Submit pre-authorization for surgery Note: Must have all 6 steps above available for pre-approval





Pre- and Post-Injection Evaluation

Very Important! Please complete this pain log following Description of Pain: your SI Joint Injection for the next four (4) Hours . Note: You may be sore from the needles, so when rating

and not any someness from the needle injection itself Please mark the figure below with an "X" at the

your pain, concentrate on the pain from your SI Joint arealocation of your pain:

AFTER YOUR INJECTIONS





Four Activities Limited

Sitting on Painful Side

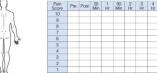
by Index Pain

Sitting to Stand

Walking

/10 For each time period, please shade the square that corresponds to your pain level:

(10 = Worst Pain Imaginable; 0 = No Pain)



10			
9			
8			
7			
6			
5			
4			
3			
2			
1			
0			

Before

Injection

After

Injection

D+ D- D+ D-

D+ D- D+ D-

/10

/10

Interpretation of Res

DAT

Patient's Comments:

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Reimbursement and Coverage Access Resources

- ISASS Policy 2016 Update
- Sample Letter to Secure Pre-Authorization
- Key Points of Reference to Assist Surgeons with Peer to Peer Reviews

ISASS Policy 2016 Update – Minimally Invasive Sacroiliac Joint Fusion

Coverage Indications, Limitations, and/or Medical Necessity

Updated July 5, 2016

(This supplements the ISASS Policy Statement – Minimally Invasive Sacrolliac Joint Fusion in IJSS)

Author: ISASS Coding & Reimbursement Task Force Chair, Morgan P. Lorio, MD, FACS

Rationale

The index 2014 ISASS Policy Statement - Minimally Invasive Sacrolliac Joint Fusion was generated out of necessity to provide an ICDP-based background and emphasize tools to ensure correct diagnosis. A timely ICD10-based 2016 Update provides a granular threshold selection with improved level of evidence and a more robust, refevand database.

Introduction

The sacrollac joints (SLI) are diarthrodial articulations of the sacrum and itium. The SLJ serves as the biomechanical mediator between the spine and pelvis. The subchondral bone, capsule, and surrounding libaments of the SLJ are intervated by spinal nerves.¹

Secolation (std) pains in lakey responsible for dronce back pain in some patients, furthermore in norms adults the prevention is ensored to be 15-50%. "Convergence on the restory patiently from the fugths 50 and the lumitors given may result in contribution of some patients from systems and the subscription of the set of the

The spectrum of pain and stakelity tion SL dysfunction is valide. Patients may be affected midity or may have staketistical functional regiments (rig. car. and a of a staff or more than the minutes, carent the staketistical functional regiments (rig. car. and the state of the

The disposis of SU pair is continued by performing a fluorescopy-guided percultaneous SU block with local anesthetic (e.g. discater). An accus netuction in typicat pain indicates a positive test suppesting that the injected joint is a pair generator. A study of patients undergoing blinded injection of saline or local matchies: showed markshy their responses to the latter, validating the test.² The Because other pathologic processes can coexist with SU pairs, physicians should discuss with patients the degree to which teatment of the SU may relieve overall pair and disability which addressing difference pairs percentors.

Occasionally, bilateral SU pain can occur. Diagnosis of bilateral SU pain should be made on the basis of typical history (bilateral symptoms), physical examination showing positive responses to SU-stressing This tanging to assigned to main providers scores coverage for acculate joint fusion with the Simonry System reported and GPT code 3/120. These as worsel places in ref within their semplits the gatematic specific information is needed. Heave insert the information periment by your platent and heir individual conditions. In addition, surgeous are accounted by individual production and experiment with this procedure and versamest is similar to act intended to replace any professional platent. It is merity to anisis with the storator of a coverage request.

Sample Letter to Secure Pre-Authorization Minimally Invasive Sacroiliac Joint Fusion Procedure 27279

Date: XXXXXX

Contact: XXXXXX Insurance Company: XXXXXX Address: XXXXXX Fax: XXXXXXX

Patient: XXXXXX Subscriber: XXXXXX Policy ID number: XXXXXX Group Number: XXXXXX

Principal Diagnosis: XXXXX Secondary Diagnosis: XXXXXX Procedure/Serrice: Sacrollia: Joint Fusion CPT code: 77.79 Minimally Invasive Sacrolliac Joint Arthrodesis with Instrumentation

RE: Request for Coverage of Minimally Invasive Sacroiliac Joint Fusion with Instrumentation

Dear (contact at payer):

I an contacting you so balled for any patient, feasory to entablish medical assessing and gain pre-architecturates for hospitalizations and urginal interventions for a minimally immain to according to the start their (medical condition). This merginal procedure will allevise their dividinitian (how tooks had), houther, and leg parts mersings from the above medical condition. In addition, my patient has the inability to ratific a string position for an average particle dividing strategies and particle methanisms of the strategies of the position for an average particle dividing strategies and particle methanisms of the strategies of the position for a average particle divide strategies of the strategies of the strategies of the medical condition must be a main contribution to observe disability. and host to observe and the strategies of the strate

I have been following (patient name) for the past (4 months or years) and their specific complaints affiliated with their condition have been the following:

Key Points of Reference to Assist Surgeons with Peer to Peer Reviews with Payers to Establish Coverage for a Minimally Invasive Sacroiliac Joint Fusion Procedure

Background

middecable, hvarating accorates priori dip-function or according has been challenging in part due to the complexity of the joint structure, the overlap with other disgencement particit cuss, and the variability of symptoms that can arise in this is table being distributed approximation of the partner interned gain and task angle of investration frame our symptoms distributed instructions of the partner can its threat and/or hypomobility reflect support due to "scapping distributed instructions". Despite these challenges, the significant para gas execution to have been excepted distributed disposition entrolds, and the development of raisonable, effecting, and less months distributed disposition entrolds, and the development of raisonable, effecting, and less months distributed modulatilises, and compared into the gains arguing in ammentarium.

There are various techniques/approaches that can be utilized to access and ture the 3 joint. The procedure that 1 perform accesses the 3 joint via a <u>minimally invasive accesses</u>. There are many clinical benefits associated with this approach. Traditional invasive methods of accessing the 31 have been replaced with these minimally invasive techniques that offse benefits to the patient without the side effects of page, none invasive procedures.

CPT Code 22279 was implemented in January 2015 and deporters "sacroliac pint stabilization for arthrodexis, percutaneous or mnimally involve (indirect visualization) includes obtaining and applying autopraft or allogatility (autochar or mensional) when genomed, includes image guidance when performed (e.g. CT or fluorocopic)". The AMA concluded that this procedure satisfield the American Medical Association's requirements to a Category (CT or do including:

- Professional society support
- Widespread utilization
 EDA approval through the S10(k) review process
- Onical efficacy is well documented in peer-reviewed literature that meets the AMA's level of
- Contract entractives were documented in pare-reviewed intractive that meets the wave since of evidence criteria

Surgical Technique

There are supply approximate, supplications, suppli

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Reimbursement Process Overview ^{rtl surgical}

Two separate claims are submitted, even if surgeon is employed by hospital or if the surgeon has ownership of ASC



Surgeon sends a bill

Payer makes TWO payments for one procedure

REMEMBER: Payment is only made if the procedure is COVERED!

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National Government Policies:

- Medicaid 44 state programs and Washington DC
- Medicare all Medicare Administrative Contractors (MACs)
- Tricare coverage for U.S. uniformed service members and their families around the world

Commercial Payer Coverage for SI Joint Fusion

- Delaware (Highmark Blue Cross Blue Shield)
- Michigan, Blue Cross Blue Shield Blue Care Network
- Nebraska, Blue Cross Blue Shield
- Pennsylvania (Highmark Blue Cross Blue Shield)
- Vermont, Blue Cross Blue Shield
- West Virginia (Highmark Blue Cross Blue Shield)
- Emblem Health of NY
- Geisinger Health Plan
- Health Partners
- Paramount Health (coverage for Advantage and Elite plans)
- HAP Alliance (for Medicare Members)
- Harvard Pilgrim

- Health New England
- Inland Empire Health Plan (IEHP)
- Kaiser Permanente (California & Northwest)

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- Kern Health Systems
- Minuteman Health
- Network Health
- PEHP Health & Benefits (Nonprofit trust providing benefits to Utah's public employees)
- Priority Health
- United Healthcare Medicare Advantage Plan
- United Healthcare (case-by-case basis, covers every case with documentation)
- Aetna
- Cigna

In Summary...



- Every insurance plan is different
- Provide updated information about the *Simmetry* system
- There are coverage access resources available
- The CCS team is here to support the coverage access process



Rebecca M. Villandry, RN, BSN Manager, Clinical Specialist Team rvillandry@rtix.com (508) 989-1872





Thank You!





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11583 R0_SImmetry Insurance and Reimbursement

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