Introduction

The meniscus is a disc of cartilage that cushions the knee. Each knee has two, one at the outer edge of the knee and another at the inner edge. These two discs act as shock absorbers. Replacing the meniscus can be done using donor material. This type of transplant is called an allograft. Meniscus transplants are usually done in patients who are too young for a total knee replacement or other reconstructive surgery. There are several factors that need to be taken into account prior to a meniscus transplant. Three of these factors are age, the amount of meniscus in the knee, and whether pain responded to other treatment. This policy discusses when meniscal allograft transplants may be considered medically necessary. Meniscal implants using collagen or man-made material are unproven (investigational). There is not enough medical evidence to show whether these types of meniscal implants are effective.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
### Policy Coverage Criteria

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Medical Necessity</th>
</tr>
</thead>
</table>
| Meniscal allograft transplantation | Meniscal allograft transplantation may be considered medically necessary in patients who have had a prior meniscectomy and have symptoms related to the affected side, when ALL of the following criteria are met:  
• Adult patients should be too young to be considered an appropriate candidate for total knee arthroplasty or other reconstructive knee surgery (eg, younger than 55 years)  
AND  
• Disabling knee pain with activity that is refractory to conservative treatment  
AND  
• Absence or near absence (more than 50%) of the existing meniscus, established by imaging or prior surgery  
AND  
• Documented minimal to absent diffuse degenerative changes in the surrounding articular cartilage (eg, Outerbridge grade II or less, and the original joint space has decreased by less than 50%)  
AND  
• Normal knee biomechanics, or alignment and stability achieved concurrently with meniscal transplantation  

Meniscal allograft transplantation may be considered medically necessary when performed in combination, either concurrently or sequentially, with treatment of focal articular cartilage lesions using any of the following procedures:  
• Autologous chondrocyte implantation  
OR  
• Osteochondral allografting  
OR  
• Osteochondral autografting  

Notes: Patients should exhibit symptoms of persistent disabling knee pain that has not shown an adequate response to physical therapy and analgesic...
medications. Uncorrected misalignment and instability of the joint are contraindications. Therefore, additional procedures, such as repair of ligaments or tendons or creation of an osteotomy for realignment of the joint, may be performed at the same time.

Severe obesity (eg, body mass index greater than 35 kg/m²) may affect outcomes due to the increased stress on weight-bearing surfaces of the joint. Meniscal allograft transplantation is typically recommended for young active patients who are too young for total knee arthroplasty.

<table>
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</table>

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other meniscal implants</td>
<td>Use of other meniscal implants incorporating materials such as collagen and polyurethane are considered investigational.</td>
</tr>
</tbody>
</table>

## Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CPT</strong></td>
<td></td>
</tr>
<tr>
<td>29882</td>
<td>Arthroscopy, knee, surgical; with meniscus repair (medial OR lateral)</td>
</tr>
<tr>
<td>29868</td>
<td>Arthroscopy, knee, surgical meniscal transplantation (includes arthrotomy for meniscal insertion), medial or lateral (eg, ReGen Collagen Scaffold)</td>
</tr>
<tr>
<td><strong>HCPCS</strong></td>
<td></td>
</tr>
<tr>
<td>G0428</td>
<td>Collagen meniscus implant procedure for filling meniscal defects (eg, CMI, collagen scaffold, Menaflex)</td>
</tr>
</tbody>
</table>

**Note:** CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

## Related Information

### Consideration of Age

The age stated in this policy for which meniscal allograft transplantation may be considered medically necessary is 55 and younger because these patients are considered too young for...
total knee arthroplasty or other reconstructive knee surgery. The age is recommended by the American Academy of Orthopaedic Surgeons.

Evidence Review

Description

Meniscal allografts and other meniscal implants (e.g., collagen or polyurethane) are intended to improve symptoms and reduce joint degeneration in patients who have had a total or partial resection of the meniscus.

Background

Meniscal cartilage is an integral structural component of the human knee. It acts to absorb shocks and provide load sharing, joint stability, congruity, proprioception, and lubrication, and also supplies nutrition of the cartilage surfaces. Total and partial meniscectomy frequently result in degenerative osteoarthritis (OA). The integrity of the menisci is particularly important in knees in which the anterior cruciate ligament (ACL) has been damaged. In these situations, the menisci act as secondary stabilizers of anteroposterior and varus-valgus translation.

Meniscal allograft transplantation (MAT) has been investigated in patients with a previous meniscectomy, or in patients who require a total or near total meniscectomy for irreparable tears. There are 3 general groups of patients who have been treated with MAT:

- Young patients with a history of meniscectomy who have symptoms of pain and discomfort associated with early OA that is localized to the meniscus-deficient compartment
- Patients undergoing ACL reconstruction in whom a concomitant meniscal transplant is intended to provide increased stability
- Young athletes with few symptoms in whom the allograft transplantation is intended to deter the development of OA. Due to the risks associated with this surgical procedure, prophylactic treatment for this purpose is not frequently recommended

Issues under study include techniques for processing and storing the grafts, proper sizing of the grafts, and the most appropriate surgical techniques (e.g., suturing or anchored with bone plugs). Four primary ways of processing and storing allografts (fresh, fresh frozen, cryopreserved,
lyophilized) have been reported. Fresh viable implants, harvested under sterile conditions, are less frequently used because the grafts must be used within a couple of days to maintain viability. Alternatively, the harvested meniscus can be fresh frozen for storage until needed. Another commonly used method, cryopreservation, freezes the graft in glycerol, which aids in preserving the cell membrane integrity and donor fibrochondrocyte viability. Cryolife (Marietta, GA) is a commercial supplier of such grafts. In addition to freezing, donor tissue may be dehydrated (freeze–dried, also called lyophilized), permitting storage at room temperature. However, lyophilized grafts have been shown to be prone to reduced tensile strength, graft shrinkage, poor rehydration, post-transplantation joint effusion, and synovitis, and are no longer used in the clinical setting. Several secondary sterilization techniques may be used, with gamma irradiation the most common. The dose of radiation considered effective has been shown to change the mechanical structure of the allograft; therefore, non-irradiated grafts from screened donors are most frequently used. In a survey conducted by the International Meniscus Reconstruction Experts Forum, 68% of surgeons preferred fresh frozen nonirradiated allografts, with 14% responding fresh viable allografts.¹

There are several techniques for MAT; most are arthroscopically assisted or all-arthroscopic. Broadly, the techniques are either all-suture fixation or bone fixation. Within the bone fixation category, the surgeon may use either bone plugs or a bone bridge. The technique used depends on laterality and the need for concomitant procedures. Patients with malalignment, focal chondral defects, and/or ligamentous insufficiency may need concomitant procedures (osteotomy, cartilage restoration, and/or ligament reconstruction, respectively).²

Tissue engineering that grows new replacement host tissue for individual patients is also being investigated. For example, the ReGen Collagen Scaffold (Ivy Sports Medicine, formerly ReGen Biologics), which may also be referred to as the Menaflex™ collagen meniscus implant or CMI™, is a re-absorbable collagen matrix composed primarily of type I collagen from bovine Achilles tendons. The implant is provided in a semi-lunar shape and trimmed to size for suturing to the remaining meniscal rim. The implant provides an absorbable collagen scaffold that is replaced by the patient’s own soft tissue; it is not intended to replace normal body structure. In addition, because it requires a meniscal rim for attachment, it is intended to fill meniscus defects after a partial meniscectomy. Other scaffold materials and cell-seeding techniques are being investigated. For example, Actifit® (Orteq) is a biodegradable polyurethane scaffold that currently has market approval in Europe. Non-absorbable and non-porous synthetic implants for total meniscus replacement are in development. One total meniscus replacement that is in early phase clinical testing is NUsurface® (Active Implants), which is composed of a polyethylene reinforced polycarbonate urethane.
Summary of Evidence

For individuals who are undergoing partial meniscectomy who receive meniscal allograft transplantation, the evidence includes systematic reviews of mostly case series. Relevant outcomes are symptoms, functional outcomes, and quality of life. The systematic reviews concluded that most studies have shown statistically significant improvements in pain and function following the procedure. The benefits have also been shown to have long-term effect (>10 years). Reviews have also reported acceptable complication and failure rates. There is no evidence that meniscal allograft transplantation can delay or prevent the development of knee osteoarthritis. A limitation of the evidence is its reliance primarily on case series. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who are undergoing partial meniscectomy and concomitant repair of malalignment, focal chondral defects, and/or ligamentous insufficiency who receive meniscal allograft transplantation, the evidence includes one systematic review of case series as well as case series published after the systematic review. Relevant outcomes are symptoms, functional outcomes, and quality of life. The systematic review concluded that pain and function improved following the procedure. One of the series published after the review showed that patients with more severe cartilage damage experienced favorable outcomes similar to patients with less cartilage damage. Another series subsequently published reported an overall 9.7-year survival of the implant. A limitation of the evidence is its reliance primarily on case series. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who are undergoing partial meniscectomy who receive collagen meniscal implants, the evidence includes two systematic reviews primarily of case series. Relevant outcomes are symptoms, functional outcomes, and quality of life. The reviews reported overall positive results with the collagen meniscus implant, but the quality of the included studies (randomized controlled trials, observational studies) is low. Radiologic evaluations have shown reduced size of the implant in a large portion of patients. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who are undergoing partial meniscectomy who receive polyurethane meniscal implants, the evidence includes a multicenter case series from the Actifit Study Group, an independently conducted pragmatic trial, and a small case series. Relevant outcomes are symptoms, functional outcomes, and quality of life. Overall improvements in pain and function have been seen following the implantation. The longest follow-up among these studies is 5 years. The studies had small sample sizes and were of low quality. Currently, no polyurethane
meniscal implants have been approved by the Food and Drug Administration for use in the United States. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Ongoing and Unpublished Clinical Trials**

Currently ongoing and unpublished trials that might influence this review are listed in *Table 1*.

**Table 1. Summary of Key Trials**

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ongoing</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT01712191</td>
<td>Treatment of the Medial Meniscus with the Treatment of the Medial Meniscus with the NUSurface® Meniscus Implant</td>
<td>150</td>
<td>Jun 2017</td>
</tr>
<tr>
<td>NCT01059409</td>
<td>The Clinical and Medico-economical Evaluation of Meniscal Allografts in the Sequelae of Total or Sub-total Meniscectomy</td>
<td>120</td>
<td>Sep 2017</td>
</tr>
<tr>
<td>NCT02136901</td>
<td>The VENUS Clinical Study (Verifying the Effectiveness of the NUSurface® System): A Multi-center, Prospective, Randomized, Interventional Superiority Clinical Study</td>
<td>37</td>
<td>Feb 2019</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.

* Denotes industry-sponsored or cosponsored trial

**Clinical Input Received from Physician Specialty Societies and Academic Medical Centers**

While the various physician specialty societies and academic medical centers may provide appropriate reviewers who collaborate with and make recommendations during this process, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.
2008 Input

In response to requests, input was received from one physician specialty society and 3 academic medical centers while this policy was under review in 2008. Although long-term effects on joint space narrowing were unknown, all of the reviewers considered meniscal allograft to be beneficial in selected patients. For example, there was evidence of short to intermediate pain relief when performed in younger patients with a prior meniscectomy who have disabling knee pain. Contraindications were noted as uncorrected instability, uncorrected malalignment, and the presence of significant articular disease.

2011 Input

In response to requests, input was received from 1 physician specialty society (3 reviewers) and 3 academic medical centers while this policy was under review in 2011. The input considered combined meniscal allograft transplantation and focal cartilage repair procedures to be medically necessary in patients younger than 55 years of age who have failed conservative treatment. The reviewers agreed that the CMI is investigational, although some considered the implant to be both investigational and medically necessary for some patients.

Practice Guidelines and Position Statements

International Meniscus Reconstruction Experts Forum

In 2015, the International Meniscus Reconstruction Experts Forum published consensus statements on the practice of meniscal allograft transplantation (MAT) (see Table 2). The Forum’s statements included guidance on indications, graft procurement and preparation, surgical technique, and rehabilitation.

Table 2. Select IMREF Consensus Statements on the Practice of MAT

<table>
<thead>
<tr>
<th>Statements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indications for MAT:</td>
</tr>
<tr>
<td>• Unicompartmental pain post-meniscectomy</td>
</tr>
<tr>
<td>• In combination with ACL reconstruction when meniscus deficient</td>
</tr>
</tbody>
</table>
### Statements

- In combination with ACR if meniscus deficient
- MAT not recommended for asymptomatic meniscus deficient patient.
- Potentially poorer outcomes expected in patients with moderate to severe OA (Kellgren-Lawrence grade ≥ 3).
- Non-irradiated fresh frozen or fresh viable grafts are recommended.
- Mechanical axis alignment should be performed prior to MAT; if mechanical axis deviation present, consider realignment osteotomy.
- Based on current evidence, superiority of 1 surgical technique over another (all-suture vs bone) is not established.

**Outcome scores should include:**

- Disease-specific: WOMAT
- Region-specific: KOOS
- Activity: Marx Activity Rating Scale
- QOL/utility: EQ-5D


### National Institute for Health and Care Excellence

The 2012 guidance from the United Kingdom’s National Institute for Health and Clinical Excellence (NICE) stated that evidence on partial replacement of the meniscus of the knee using a biodegradable scaffold raised no major safety concerns, but evidence for any advantage of the procedure over standard surgery was limited. Therefore, NICE recommends that this procedure should only be used with special arrangements for clinical governance, consent and audit or research.

### American Academy of Orthopaedic Surgeons

The American Academy of Orthopaedic Surgeons stated in 2009 that a meniscal transplant may be recommended for active people younger than 55 years old, with the goal of replacing the meniscus cushion before the articular cartilage is damaged. The website also notes that “synthetic (artificial) meniscal tissue has been tried, but there is conflicting information at this time.”
Medicare National Coverage

In May 2010, the Centers for Medicare and Medicaid Services (CMS) issued a national non-coverage determination for the collagen meniscus implant. A number of concerns regarding efficacy and safety were raised in the CMS analysis that compared data reported to the FDA and published data. These included an increased number of reoperations and a higher serious adverse event rate than the control group. CMS concluded that the collagen meniscus implant does not improve health outcomes in the Medicare population and determined that the collagen meniscus implant is not reasonable and necessary for the treatment of meniscal injury/tear.

Regulatory Status

Collagen Meniscus Implants

The ReGen Collagen Scaffold (CS) received 510(k) marketing clearance from FDA in 2008. The marketing clearance was based on the decision that this collagen scaffold was substantially equivalent to existing predicate absorbable surgical mesh devices. The ReGen Collagen Scaffold (also known as Menaflex™ CMI) was the only CMI with FDA clearance at that time. Amid controversy about the 510(K) clearance for the ReGen Collagen Scaffold, FDA initiated a review of the clearance process for this device. In October 2010, FDA announced that the device should not have been cleared for marketing, as the Menaflex™ device is intended to be used for different purposes and is technologically dissimilar from devices already on the market (predicate devices). The manufacturer appealed the decision, and won its appeal in 2014. The product, now called CMI®, is manufactured by Ivy Sports Medicine. CMI® is the only FDA-approved collagen meniscus product currently on the market.

FDA product code: OLC.

Polyurethane Meniscal Implant

There are no FDA-approved polyurethane meniscal implants currently on the market in the United States. Actifit® is approved for marketing in Europe.


<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>01/97</td>
<td>Add to Surgery Section - New Policy</td>
</tr>
<tr>
<td>04/14/98</td>
<td>Replace Policy - Reviewed with changes; description, rationale clarified</td>
</tr>
<tr>
<td>06/25/98</td>
<td>Replace Policy - Revision of title from Meniscal Allograft</td>
</tr>
<tr>
<td>10/09/01</td>
<td>Replace Policy - Reviewed; policy statement unchanged.</td>
</tr>
<tr>
<td>03/11/03</td>
<td>Replace Policy - Policy replaces CP.MP.BC.7.01.15. Meniscal allograft transplantation may be considered medically necessary.</td>
</tr>
<tr>
<td>08/12/03</td>
<td>Replace Policy - Policy statement unchanged; rationale section and references updated.</td>
</tr>
<tr>
<td>05/11/04</td>
<td>Replace Policy - Policy reviewed; no change to policy statement; references updated.</td>
</tr>
<tr>
<td>09/01/04</td>
<td>Replace Policy - Policy renumbered from PR.7.01.117. No changes to dates.</td>
</tr>
<tr>
<td>05/10/05</td>
<td>Replace Policy - Policy reviewed; no change to policy statement.</td>
</tr>
<tr>
<td>04/11/06</td>
<td>Replace Policy - Policy reviewed; no change to policy statement.</td>
</tr>
<tr>
<td>06/06/09</td>
<td>Disclaimer and Scope update - No other changes.</td>
</tr>
<tr>
<td>04/10/07</td>
<td>Replace Policy - Policy updated with literature review; reference added. No change in policy statement.</td>
</tr>
<tr>
<td>05/13/08</td>
<td>Replace Policy - Policy updated with literature search; no change to the policy statement. Policy Guidelines updated; obesity deleted (3PrdP bullet), and “who have &gt;early grade III arthritis” deleted as this is a duplicate of the 1PstP bullet.</td>
</tr>
<tr>
<td>03/10/09</td>
<td>New BC Policy - Policy statement in alignment with the PR version, therefore decision was made to convert back to the BC version. Policy replaces PR.7.01.517.</td>
</tr>
<tr>
<td>01/12/10</td>
<td>Replace Policy - Policy updated with literature search. Policy statement added “collagen implant considered investigational”. Collagen Meniscus implant added to the title. References added.</td>
</tr>
<tr>
<td>06/13/11</td>
<td>Replace Policy - Policy updated with literature review through February 2011; references added and reordered; clinical input reviewed; allograft considered medically necessary in patients under 55 years; combined procedures may be medically necessary; “lasting at least 6 months” removed from Policy Guidelines. ICD-10 codes added to policy.</td>
</tr>
<tr>
<td>05/08/12</td>
<td>Replace policy. Policy updated with literature review through December 2011; Rationale section revised; reference 17 added and references reordered; some references removed. Policy statement for meniscal allograft transplantation changed from investigational to medically necessary when combination procedures performed.</td>
</tr>
<tr>
<td>08/15/12</td>
<td>Remove Related Policies: 7.01.48, it was archived.</td>
</tr>
<tr>
<td>09/27/12</td>
<td>Remove Related Policies: 7.01.506; ICD-10 codes are now effective 10/01/2014.</td>
</tr>
<tr>
<td>05/13/13</td>
<td>Replace policy. Policy updated with literature review through January 30, 2013; references 21-24 added; title and investigational statement changed from “collagen”</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
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<td>---------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>06/14/13</td>
<td>Update Related Policies. Add 8.01.52.</td>
</tr>
<tr>
<td>07/16/13</td>
<td>Update Related Policies. Add 7.01.549</td>
</tr>
<tr>
<td>10/17/13</td>
<td>Update Related Policies. Add 1.03.501.</td>
</tr>
<tr>
<td>05/12/14</td>
<td>Annual Review. Policy updated with literature review through February 21, 2014. Reference 23 added; others renumbered/removed. Policy statements unchanged.</td>
</tr>
<tr>
<td>07/24/14</td>
<td>Update Related Policies. Change title to 7.0.549.</td>
</tr>
<tr>
<td>09/17/14</td>
<td>Update Related Policies. Change title to 7.01.550.</td>
</tr>
<tr>
<td>03/24/15</td>
<td>Update Related Policies. Change title to 7.01.549.</td>
</tr>
<tr>
<td>05/12/15</td>
<td>Annual Review. Policy updated with literature review through January 28, 2015; Rationale extensively revised; references 10, 17, and 21 added; policy statements unchanged. ICD-9 and ICD-10 diagnosis and procedure codes removed; these are not utilized in policy adjudication.</td>
</tr>
<tr>
<td>12/01/16</td>
<td>Minor update, approved November 8, 2016. Language added to the rationale section to indicate that the scope of this policy applies to those age 55 or younger based on the recommendation of the American Academy of Orthopaedic Surgeons.</td>
</tr>
<tr>
<td>07/01/17</td>
<td>Annual Review, approved June 6, 2017. Policy moved into the new format. Policy updated with literature review through February 23, 2017; references 1, 6, 16-17, 19, 27, and 30 added. Removed CPT code 27403. Policy statements unchanged.</td>
</tr>
</tbody>
</table>

**Disclaimer:** This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2017 Premera All Rights Reserved.

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Toll free 855-332-4535, Fax 425-918-5952. TTY 800-842-5357
Email AppealsDepartmentinquines@Premera.com

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https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:
U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)
Complaint forms are available at:

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Appelez le 800-722-1471 (TTY: 800-842-5357).

Kreyòl ayisyen (Creole):

Deutsche (German):

Hmoob (Hmong):

Iloko (Ilocano):
Daytoy a Pakdaar ket naglaon iti Napateg nga Impormasion. Daytoy a pakdaar mabalini nga adda ket naglaon iti napateg nga impormasion maipanggep iti aplikasyonwoy wenno coverage babaen iti Premera Blue Cross. Daytoy ket mabalini dagiti importante a pelsa iti daytoy a pakdaar. Mabalini nga adda rumbeng nga aramideng nga adda sakkay dagiti partikular a naituding nga adda aldaw tapno mapagtalagmaydo ti coverage ti salun-atyo wenno tulong kadagiti gastos. Adda karbenganyo a mangala iti daytoy nga impormasion ken tulong ti bukodyo a pagasasao nga awan ti bayadanyo. Tumawag ti numero nga 800-722-1471 (TTY: 800-842-5357).

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037338 (07-2016)
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유지하거나

관하여

familiarización en su idioma

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Premera Blue Cross (TTY: 800-842-5357).

Premera Blue Cross (TTY: 800-842-5357).