MEDICAL POLICY – 7.01.569
Autologous Chondrocyte Implantation for Focal Articular Cartilage Lesions

BCBSA Ref. Policy: 7.01.48
Effective Date: July 1, 2019
Last Revised: June 4, 2019
Replaces: 7.01.48

RELATED MEDICAL POLICIES:
1.01.10 Continuous Passive Motion in the Home Setting
7.01.15 Meniscal Allografts and Other Meniscal Implants
7.01.570 Autografts and Allografts in the Treatment of Focal Articular Cartilage Lesions
8.01.52 Orthopedic Applications of Stem Cell Therapy (Including Allografts and Bone Substitutes Used with Autologous Bone Marrow)
11.01.524 Site of Service: Select Surgical Procedures

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | DOCUMENTATION REQUIREMENTS | CODING
RELATED INFORMATION | EVIDENCE REVIEW | REFERENCES | HISTORY

∞ Clicking this icon returns you to the hyperlinks menu above.

Introduction

Cartilage is firm, rubbery tissue that covers the ends of bones at the joints. Damaged cartilage can cause pain and adversely impact how the joint works. One treatment to repair knee cartilage involves using a person’s own cartilage cells, which are called chondrocytes. The treatment requires two steps. In the first step, cartilage cells are removed from the knee. They are sent to a lab where, over the next several weeks, a large number of cartilage cells are grown. The second step requires open surgery. The damaged cartilage is removed from the end of the bone, a sheet of special material is placed over that area, and the cartilage cells that were grown in the lab are suspended within a liquid and injected in the space between the bone and the material. This policy describes when this surgery may be considered medically necessary for the knee. It has not been well studied in other locations in the body and is considered unproven (investigational) for other joints.

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

We will review for medical necessity these elective surgical procedures.

We also will review the site of service for medical necessity. Site of service is defined as the location where the surgical procedure is performed, such as an off campus-outpatient hospital or medical center, an on campus-outpatient hospital or medical center, an ambulatory surgical center, or an inpatient hospital or medical center.

<table>
<thead>
<tr>
<th>Site of Service for Elective Surgical Procedures</th>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Medically necessary sites of service:</strong></td>
<td></td>
</tr>
<tr>
<td>• Off campus-outpatient hospital/medical center</td>
<td>Certain elective surgical procedures will be covered in the most appropriate, safe, and cost effective site. These are the preferred medically necessary sites of service for certain elective surgical procedures.</td>
</tr>
<tr>
<td>• On campus-outpatient hospital/medical center</td>
<td></td>
</tr>
<tr>
<td>• Ambulatory Surgical Center</td>
<td></td>
</tr>
<tr>
<td><strong>Inpatient hospital/medical center</strong></td>
<td>Certain elective surgical procedures will be covered in the most appropriate, safe, and cost-effective site. This site is considered medically necessary only when the patient has a clinical condition which puts him or her at increased risk for complications including any of the following (this list may not be all inclusive):</td>
</tr>
<tr>
<td></td>
<td>• Anesthesia Risk</td>
</tr>
<tr>
<td></td>
<td>o ASA classification III or higher (see definition)</td>
</tr>
<tr>
<td></td>
<td>o Personal history of complication of anesthesia</td>
</tr>
<tr>
<td></td>
<td>o Documentation of alcohol dependence or history of cocaine use</td>
</tr>
<tr>
<td></td>
<td>o Prolonged surgery (&gt;3 hours)</td>
</tr>
<tr>
<td></td>
<td>• Cardiovascular Risk</td>
</tr>
<tr>
<td>Site of Service for Elective Surgical Procedures</td>
<td>Medical Necessity</td>
</tr>
<tr>
<td>------------------------------------------------</td>
<td>-------------------</td>
</tr>
</tbody>
</table>
| o Uncompensated chronic heart failure *(NYHA class III or IV)* | • Liver Risk  
| o Recent history of myocardial infarction (MI) (<3 months) | o Advance liver disease (MELD Score > 8)** |
| o Poorly controlled, resistant hypertension* | • Pulmonary Risk  
| o Recent history of cerebrovascular accident (< 3 months) | o Chronic obstructive pulmonary disease (COPD) (FEV1 <50%) |
| o Increased risk for cardiac ischemia (drug eluting stent placed < 1 year or angioplasty <90 days) | o Poorly controlled asthma (FEV1 <80% despite treatment) |
| o Symptomatic cardiac arrhythmia despite medication | o Moderate to severe obstructive sleep apnea (OSA)*** |
| o Significant valvular heart disease | • Renal Risk  
| • Liver Risk | o End stage renal disease (on dialysis) |
| o Advance liver disease (MELD Score > 8)** | • Other  
| • Pulmonary Risk | o Morbid obesity (BMI ≥ 50) |
| o Chronic obstructive pulmonary disease (COPD) (FEV1 <50%) | o Pregnancy |
| o Poorly controlled asthma (FEV1 <80% despite treatment) | o Bleeding disorder (requiring replacement factor, blood products, or special infusion product [DDAVP**** does not meet this criteria]) |
| o Moderate to severe obstructive sleep apnea (OSA)*** | o Anticipated need for transfusion(s) |

* 3 or more drugs to control blood pressure  
*** Moderate-AHI≥15 and ≤ 30, Severe-AHI ≥30  
**** DDAVP-Deamino-Delta-D-Arginine Vasopressin (Desmopressin)  

| Inpatient hospital/medical center | This site of service is considered NOT medically necessary for certain elective surgical procedures when the site of service criteria listed above are not met. |
### Procedure

**Medical Necessity**

- Autologous chondrocyte implantation may be considered medically necessary when ALL of the following criteria are met:
  - Severe disabling knee pain and loss of knee function that interferes with activities of daily living or work ability is present
  - Documented trial and failure of conservative therapy for at least 3 months (includes NSAIDs, and at least 6 PT visits)
  - Patient is age 15 years or older or younger than 55 years of age
  - Body mass index (BMI) is 35 or less
  - Focal, full-thickness (grade III or IV Outerbridge scale) unipolar lesions of the weight-bearing surface of the femoral condyles, trochlea, or patella that are at least 1.5 cm² in size
  - Documented minimal to absent degenerative changes in the surrounding articular cartilage (Outerbridge grade II or less), and normal-appearing hyaline cartilage surrounding the border of the defect
  - All of the following are present on exam:
    - Stable knee with intact or reconstructed ligaments (ACL or PCL) or repairs are planned with the procedure (see Related Information below)
    - Normal joint alignment
    - Normal joint space

### Procedure

**Investigational**

- Autologous chondrocyte implantation for all other joints, including the talar, and any indications other than those listed above is considered investigational.

### Documentation Requirements

The patient’s medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following:

- Office visit notes that contain the relevant history and physical exam, including the size of and description of the lesion and the surrounding articular cartilage and border of the defect

**AND**

- BMI

**AND**
Documentation Requirements

- MRI results that align with modified Outerbridge classification

Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td></td>
</tr>
<tr>
<td>27412</td>
<td>Autologous chondrocyte implantation, knee</td>
</tr>
<tr>
<td>29870</td>
<td>Arthroscopy, knee, diagnostic, with or without synovial biopsy (separate procedure)</td>
</tr>
<tr>
<td>29877</td>
<td>Arthroscopy, knee, surgical; debridement/shaving of articular cartilage (chondroplasty)</td>
</tr>
<tr>
<td>29879</td>
<td>Arthroscopy, knee, surgical; abrasion arthroplasty (includes chondroplasty where necessary) or multiple drilling or microfracture</td>
</tr>
<tr>
<td>29880</td>
<td>Arthroscopy, knee, surgical; with meniscectomy (medial AND lateral, including any meniscal shaving) including debridement/shaving of articular cartilage (chondroplasty), same or separate compartment(s), when performed</td>
</tr>
<tr>
<td>29881</td>
<td>Arthroscopy, knee, surgical; with meniscectomy (medial OR lateral, including any meniscal shaving) including debridement/shaving of articular cartilage (chondroplasty), same or separate compartment(s), when performed</td>
</tr>
<tr>
<td>29882</td>
<td>Arthroscopy, knee, surgical; with meniscus repair (medial OR lateral)</td>
</tr>
<tr>
<td>29883</td>
<td>Arthroscopy, knee, surgical; with meniscus repair (medial AND lateral)</td>
</tr>
<tr>
<td>HCPCS</td>
<td></td>
</tr>
<tr>
<td>J7330</td>
<td>Autologous cultured chondrocytes, implant</td>
</tr>
<tr>
<td>S2112</td>
<td>Arthroscopy, knee, surgical, for harvesting of cartilage (chondrocyte cells)</td>
</tr>
</tbody>
</table>

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Related Information

For smaller lesions (eg, <4 cm²), if débridement is the only prior surgical treatment, then consideration should be given to marrow-stimulating techniques before autologous chondrocyte implantation (ACI) is performed.
The average defect size reported in the literature is about 5 cm²; many studies treated lesions as large as 15 cm².

Severe obesity (eg, body mass index >35 kg/m²) may affect outcomes due to the increased stress on weight-bearing surfaces of the joint.

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. In addition, meniscal allograft transplantation may be performed in combination, either concurrently or sequentially, with ACI. The charges for the culturing component of the procedure are submitted as part of the hospital bill.

The entire matrix-induced ACI procedure consists of 4 steps: (1) initial arthroscopy and biopsy of normal cartilage, (2) culturing of chondrocytes on an absorbable collagen matrix, (3) a separate arthrotomy to place the implant, and (4) postsurgical rehabilitation. The initial arthroscopy may be scheduled as a diagnostic procedure; as part of this procedure, a cartilage defect may be identified, prompting biopsy of normal cartilage in anticipation of a possible chondrocyte transplant. The biopsied material is then sent for culturing and returned to the hospital when the implantation procedure (ie, arthrotomy) is scheduled.

**Definition of Terms**

**American Society of Anesthesiologists (ASA) Score:**

ASA 1 A normal healthy patient.
ASA 2 A patient with mild systemic disease.
ASA 3 A patient with severe systemic disease.
ASA 4 A patient with severe systemic disease that is a constant threat to life.
ASA 5 A moribund patient who is not expected to survive

**New York Heart Association (NYHA) Classification:**

Class I No symptoms and no limitation in ordinary physical activity, eg, shortness of breath when walking, climbing stairs etc.
Class II Mild symptoms (mild shortness of breath and/or angina) and slight limitation during ordinary activity.
Class III Marked limitation in activity due to symptoms, even during less-than-ordinary activity, eg, walking short distances (20–100 m). Comfortable only at rest.
Class IV Severe limitations. Experiences symptoms even while at rest. Mostly bedbound patients
Modified Outerbridge Classification

The Outerbridge classification is a grading system for joint cartilage breakdown. It has been modified to report MRI results, and was originally used for arthroscopy results. Below is correlation between the two.

<table>
<thead>
<tr>
<th>Grade</th>
<th>MRI Results</th>
<th>Arthroscopy Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>GRADE I</td>
<td>focal areas of hyperintensity with normal contour</td>
<td>cartilage with softening and swelling</td>
</tr>
<tr>
<td>GRADE II</td>
<td>blister-like swelling/fraying of articular cartilage extending to surface</td>
<td>fragmentation and fissuring within soft areas of articular cartilage</td>
</tr>
<tr>
<td>GRADE III</td>
<td>partial thickness cartilage loss with focal ulceration</td>
<td>partial thickness cartilage loss with fibrillation (crab-meat appearance)</td>
</tr>
<tr>
<td>GRADE IV</td>
<td>full thickness cartilage loss with underlying bone reactive changes</td>
<td>cartilage destruction with exposed subchondral bone*</td>
</tr>
</tbody>
</table>

*Subchondral bone is the bone underneath the white joint cartilage

Consideration of Age

The age range listed in this policy, 15 to 55 years of age, takes in to consideration skeletal maturity and the age at which total knee replacements are considered. Skeletal maturity is reached around the age of 15, and adults younger than 55 are generally considered unsuitable candidates for total knee replacement.

Evidence Review

Description

A variety of procedures are being developed to resurface articular cartilage defects. Autologous chondrocyte implantation (ACI) involves harvesting chondrocytes from healthy tissue, expanding the cells in vitro, and implanting the expanded cells into the chondral defect. Second- and third-generation techniques include combinations of autologous chondrocytes, scaffolds, and growth factors.
Background

Articular Cartilage Lesions

Damaged articular cartilage typically fails to heal on its own and can be associated with pain, loss of function, and disability and may lead to debilitating osteoarthritis over time. These manifestations can severely impair a patient’s activities of daily living and adversely affect quality of life.

Treatment

Conventional treatment options include débridement, subchondral drilling, microfracture, and abrasion arthroplasty. Débridement involves the removal of synovial membrane, osteophytes, loose articular debris, and diseased cartilage and is capable of producing symptomatic relief. Subchondral drilling, microfracture, and abrasion arthroplasty attempt to restore the articular surface by inducing the growth of fibrocartilage into the chondral defect. Compared with the original hyaline cartilage, fibrocartilage has less capability to withstand shock or shearing force and can degenerate over time, often resulting in the return of clinical symptoms. Osteochondral grafts and autologous chondrocyte implantation (ACI) attempt to regenerate hyaline-like cartilage and thereby restore durable function. Osteochondral grafts for the treatment of articular cartilage defects are discussed in a separate medical policy (see Related Policies above).

With ACI, a region of healthy articular cartilage is identified and biopsied through arthroscopy. The tissue is sent to a facility licensed by the U.S. Food and Drug Administration (FDA) where it is minced and enzymatically digested, and the chondrocytes are separated by filtration. The isolated chondrocytes are cultured for 11 to 21 days to expand the cell population, tested, and then shipped back for implantation. With the patient under general anesthesia, an arthrotomy is performed, and the chondral lesion is excised up to the normal surrounding cartilage. Methods to improve the first-generation ACI procedure have been developed, including the use of a scaffold or matrix-induced autologous chondrocyte implantation (MACI) composed of biocompatible carbohydrates, protein polymers, or synthetics. The only FDA-approved MACI product to date is supplied in a sheet, which is cut to size and fixed with fibrin glue. This procedure is considered technically easier and less time consuming than the first-generation technique, which required suturing of a periosteal or collagen patch and injection of chondrocytes under the patch.
Desired features of articular cartilage repair procedures are the ability (1) to be implanted easily, (2) to reduce surgical morbidity, (3) not to require harvesting of other tissues, (4) to enhance cell proliferation and maturation, (5) to maintain the phenotype, and (6) to integrate with the surrounding articular tissue. In addition to the potential to improve the formation and distribution of hyaline cartilage, use of a scaffold with MACI eliminates the need for harvesting and suture of a periosteal or collagen patch. A scaffold without cells may also support chondrocyte growth.

**Summary of Evidence**

For individuals who have focal articular cartilage lesion(s) of the weight-bearing surface of the femoral condyles, trochlea, or patella who receive autologous chondrocyte implantation (ACI), the evidence includes systematic reviews, randomized controlled trials (RCTs), and prospective observational studies. Relevant outcomes are symptoms, change in disease status, morbid events, functional outcomes, and quality of life. There is a large body of evidence on ACI for the treatment of focal articular cartilage lesions of the knee. For large lesions, ACI results in better outcomes than microfracture, particularly in the long term. In addition, there is a limit to the size of lesions that can be treated with osteochondral autograft transfer, due to a limit on the number of osteochondral cores that can be safely harvested. As a result, ACI has become the established treatment for large articular cartilage lesions in the knee. In 2017, first-generation ACI with a collagen cover was phased out and replaced with an ACI preparation that seeds the chondrocytes onto a bioresorbable collagen sponge. Although the implantation procedure for this second-generation ACI is less technically demanding, studies to date have not shown improved outcomes compared with first-generation ACI. Some evidence has suggested an increase in hypertrophy (overgrowth) of the new implant that may exceed that of the collagen membrane covered implant. Long-term studies with a larger number of patients will be needed to determine whether this hypertrophy impacts graft survival. Based on mid-term outcomes that approximate those of first-generation ACI and the lack of alternatives, second-generation ACI may be considered an option for large disabling full-thickness cartilage lesions of the knee. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have focal articular cartilage lesions of joints other than the knee who receive ACI, the evidence includes systematic reviews of case series. Relevant outcomes are symptoms, change in disease status, morbid events, functional outcomes, and quality of life. The greatest amount of literature is for ACI of the talus. Comparative trials are needed to determine
whether ACI improves outcomes for lesions in joints other than the knee. The evidence is insufficient to determine the effects of the technology on health outcomes.

Ongoing and Unpublished Clinical Trials

Some currently 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>NCT01066702</td>
<td>A Randomized Comparison of NeoCart to Microfracture for the Repair of Articular Cartilage Injuries in the Knee</td>
<td>245</td>
<td>Jun 2020</td>
</tr>
<tr>
<td>NCT01222559</td>
<td>Prospective, Randomised, Open Label, Multicentre Phase-III Clinical Trial to Compare the Efficacy and Safety of the Treatment With the Autologous Chondrocyte Transplantation Product co.Don Chondrosphere (ACT3D-CS) With Microfracture in Subjects With Cartilage Defects of the Knee With a Defect Size Between 1 and 4 cm²</td>
<td>102</td>
<td>Dec 2020</td>
</tr>
<tr>
<td>NCT01656902</td>
<td>A Prospective Randomized Controlled Multicenter Phase-III Clinical Study to Evaluate the Safety and Effectiveness of NOVOCART® 3D Plus Compared to the Standard Procedure Microfracture in the Treatment of Articular Cartilage Defects of the Knee</td>
<td>261</td>
<td>Mar 2021</td>
</tr>
<tr>
<td>NCT01957722</td>
<td>A Phase 3, Prospective, Randomized, Partially Blinded Multi-Center Study to Measure the Safety and Efficacy of NOVOCART 3D Compared to Microfracture in the Treatment of Articular Cartilage Defects</td>
<td>233</td>
<td>Aug 2021</td>
</tr>
<tr>
<td><strong>Unpublished</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT01251588</td>
<td>An Extension Protocol for Participants of Genzyme-Sponsored Prospective, Randomized, Open-Label, Parallel-Group, Multicenter Study of Matrix-Induced Autologous Chondrocyte Implantation (MACI® Implant) for the Treatment of Symptomatic Articular Cartilage Defects of the Femoral Condyle Including the Trochlea for the Repair of Articular Cartilage Injuries in the Knee</td>
<td>128</td>
<td>Mar 2015 (completed)</td>
</tr>
</tbody>
</table>
Clinical Input Received from Physician Specialty Societies and Academic Medical Centers

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

2015 Input

In response to requests, input was received from 2 physician specialty societies (6 reviewers) and 4 academic medical centers while this policy was under review in 2015. Input was generally supportive of the use of autologous chondrocyte implantation (ACI) for large patellar lesions, although the degree of support varied. Reviewers indicated that outcomes were improved when realignment procedures were performed concurrently with ACI of the patella, and that success rates were lower when using ACI after a prior microfracture. Most reviewers recommended that a prior surgical procedure not be required for lesions greater than 4 cm$^2$.

2011 Input

In response to requests, input was received from 2 physician specialty societies and 3 academic medical centers while this policy was under review in 2011. Input was generally in agreement with the stated criteria for ACI, except the following: input was mixed on the requirement for an inadequate response to a prior surgical procedure and the requirement for an absence of meniscal pathology. Input was also mixed on the investigational status of ACI in patellar and talar joints.
Practice Guidelines and Position Statements

American Academy of Orthopaedic Surgeons

In guidelines on the diagnosis and treatment of osteochondritis dissecans, the American Academy of Orthopaedic Surgeons (AAOS) (2010) did not recommend for or against a specific cartilage repair technique in symptomatic skeletally immature or mature patients with an unsalvageable osteochondritis dissecans lesion. This finding of insufficient evidence was based on a systematic review that found four level IV studies addressing cartilage repair techniques for an unsalvageable osteochondritis dissecans lesion. Because each level IV article used different techniques, different outcome measures, and differing lengths of follow-up, the Academy deemed the evidence for any specific technique to be inconclusive.

National Institute for Health and Care Excellence

The National Institute for Health and Care Excellence (2018) updated its 2005 guidance on the use of autologous chondrocyte implantation. The Institute

“... as an option for treating symptomatic articular cartilage defects of the femoral condyle and patella of the knee (International Cartilage Repair Society grade III or IV) in adults, only if:

- the person has not had previous surgery to repair articular cartilage defects;
- there is minimal osteoarthritic damage to the knee (as assessed by clinicians experienced in investigating knee cartilage damage using a validated measure for knee osteoarthritis);
- the defect is over 2 cm²

Medicare National Coverage

There is no national coverage determination.

Regulatory Status

The culturing of chondrocytes is considered by the FDA to fall into the category of manipulated autologous structural cells, which are subject to a biologic licensing requirement. In 1997, Carticel® (Genzyme; now Vericel) received FDA approval for the repair of clinically significant,
“...symptomatic cartilaginous defects of the femoral condyle (medial, lateral or trochlear) caused by acute or repetitive trauma....”

In December 2016, MACI® (Vericel) received the FDA approval for “the repair of symptomatic, single or multiple full-thickness cartilage defects of the knee with or without bone involvement in adults.” MACI® consists of autologous chondrocytes which are cultured onto a bioresorbable porcine-derived collagen membrane. In 2017, production of Carticel® was phased out, and MACI® is the only ACI product available in the United States.

A number of other second-generation methods for implanting autologous chondrocytes in a biodegradable matrix are currently in development or testing or are available outside of the United States. They include Atelocollagen (Koken), a collagen gel; Bioseed® C (BioTissue Technologies), a polymer scaffold; CaReS (Ars Arthro), collagen gel; Cartilix (Biomet), a polymer hydrogel; Chondron (Sewon Cellontech), a fibrin gel; Hyalograft C (Fidia Advanced Polymers), a hyaluronic acid-based scaffold; NeoCart (Histogenics), an ACI with a 3-dimensional chondromatrix in a phase 3 trial; and Novocart®3D (Aesculap Biologics), a collagen-chondroitin sulfate scaffold in a phase 3 trial. ChondroCelect® (TiGenix), characterized as a chondrocyte implantation with a completed phase 3 trial, uses a gene marker profile to determine in vivo cartilage-forming potential and thereby optimizes the phenotype (eg, hyaline cartilage vs fibrocartilage) of the tissue produced with each ACI cell batch. Each batch of chondrocytes is graded based on the quantitative gene expression of a selection of positive and negative markers for hyaline cartilage formation. Both Hyalograft C and ChondroCelect® have been withdrawn from the market in Europe.

References


<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>07/01/19</td>
<td>New policy, approved June 4, 2019. This policy replaces 7.01.48. Policy created with literature review through February 2019. Updated age to 15 years of age or older rather than 16. Other minor edits made for clarity only.</td>
</tr>
</tbody>
</table>

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  - Information written in other languages

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200 Independence Avenue SW, Room S09F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

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