

# 2023

## Reimbursement

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FOCUSED  
ULTRASOUND  
FOUNDATION

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## Overview

Since very few patients have the capacity to pay out-of-pocket for their medical care, reimbursement of medical procedures by a government or private insurer is a critical element of the healthcare ecosystem and the adoption of new technologies like focused ultrasound. Despite its importance, the process of medical reimbursement is not as straightforward as simply sending a bill and receiving payment. As patients and physicians alike have experienced, the process of getting reimbursed for a medical procedure can be a complicated system that involves a labyrinth of policies and processes.

Because insurers often require preauthorization for procedures and because coverage is regional in some countries, we strongly recommend that patients confirm insurance coverage with their insurer prior to undergoing treatment. The good news is that, despite the complexities of reimbursement, the use of focused ultrasound to treat a wide range of diseases is available in many countries. Currently in the US, there is some level of insurance coverage of focused ultrasound to treat bone metastases, essential tremor, Parkinson's disease, uterine fibroids, and prostate cancer.

Europe, in its broadest geographical definition, comprises about 50 countries, each with its own legislation and healthcare system. Even within the biggest block of countries—the European Union with 27 member states—healthcare delivery and related funding is organized on a national level, and in some countries, even on a regional level. To assess the full scope of focused ultrasound-based procedure reimbursement in Europe, one must look at individual countries and their respective healthcare governance.

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## Global and US Reimbursement Levels

2022

Reimbursement

17

Countries offer varying levels of reimbursement

32

Indications worldwide have regulatory approvals

44%

have reimbursement

with varying levels in at least one country

8

Indications have US FDA approvals

63%

have reimbursement

5 indications are insured in some states

## REIMBURSEMENT

### Insurance Coverage by Region\*

Indications	North America	Europe	Asia	Oceania
<b>Benign prostatic hyperplasia</b>		France Germany	Saudi Arabia Singapore	Australia
<b>Bone metastases</b>	United States <sup>1</sup>	Germany Italy <sup>3</sup>	Israel Malaysia Saudi Arabia South Korea	Australia
<b>Breast tumors, benign</b>		Germany <sup>4</sup>		
<b>Breast tumors, malignant</b>		Germany <sup>4</sup>		
<b>Desmoid tumors</b>		Germany <sup>4</sup>		
<b>Essential tremor</b>	Canada <sup>2</sup> United States <sup>1</sup>	Denmark Germany Italy <sup>3</sup> Switzerland United Kingdom	Israel Japan	
<b>Neuropathic pain</b>		Germany Italy <sup>3</sup> Switzerland	Israel	
<b>Osteoid osteoma</b>		Germany Italy <sup>3</sup>		
<b>Pancreatic tumors</b>		Germany <sup>4</sup>		
<b>Parkinson's disease, tremor</b>	United States <sup>1</sup>	Germany Italy <sup>3</sup> Switzerland	Israel Japan	
<b>Prostate cancer</b>	United States <sup>1</sup>	France Germany United Kingdom	Japan Saudi Arabia Singapore South Korea	Australia

\* All coverage decisions are conditional. The most current policy documents from the individual insurers should be referenced for a complete description.














1 A detailed analysis of government and private coverage status in individual US states is available on pages XII.8–XII.12 of this section.

2 In Canada, essential tremor and uterine fibroids are covered only in the province of Ontario.

3 In Italy: Essential tremor and TDPD are covered in Sicily, Abruzzo, and Lombardia. Neuropathic pain is covered in Milan. Bone metastases and osteoid osteoma are covered in Lombardia, Emilia Romagna, Lazio, and Abruzzo. Uterine fibroids are covered by all regions that provide "essential levels of assistance": Abruzzo, Basilicata, Emilia Romagna, Lazio, Lombardia, Marche, Tuscany, and Umbria.

4 Codes that are not specific to FUS procedures, but can be used to bill for them.

## Insurance Coverage by Region\* continued

Indications	North America	Europe	Asia	Oceania
<b>Thyroid nodules</b>		 Germany <sup>4</sup>		
<b>Uterine fibroids</b>	 Canada <sup>2</sup>  United States <sup>1</sup>	 Germany  Italy <sup>3</sup>	 China  Israel  Malaysia  Saudi Arabia  South Korea  Vietnam	 Australia
<b>Varicose veins</b>		 Germany <sup>4</sup>		

## Reimbursement

In medical care, reimbursement is the process of paying for healthcare services including office visits, labs/tests, imaging, and procedures, after an encounter has taken place. This is a significant difference between healthcare and other industries because the provider is not paid until after rendering a service.

After a physician or healthcare provider performs a procedure in a hospital or clinic as a treatment for a medical condition, they then send the bill to a payer. In a setting of many rules, the payer reimburses the physician, hospital/clinic, or patient for all or part of the fee for providing the treatment. Payers include private insurance companies, self-funded health plans, and government entities.

The process is not as simple as sending a bill and receiving payment. Payers collect and analyze data on patient outcomes and healthcare provider costs. They do not reimburse all procedures. Many procedures must have prior authorization to be considered for payment. Before payers will cover a new procedure or treatment, they require proof that, compared to the current standard of care, the new treatment is safe, is superior or equal in efficacy, and costs less in the short term or over an extended period of time.

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## REIMBURSEMENT

### Insurance Coverage by Country\*

	BPH	Bone metastases	Breast tumors, benign	Breast tumors, malignant	Desmoid tumors	Essential tremor	Neuropathic pain	Osteoid osteoma	Pancreatic tumors	Parkinson's tremor
<b>North America</b>										
 Canada <sup>2</sup>						■				
 United States <sup>1</sup>		■				■				■
<b>Europe</b>										
 Denmark						■				
 France	■									
 Germany	■	■	■ <sup>4</sup>	■ <sup>4</sup>	■ <sup>4</sup>	■	■	■	■ <sup>4</sup>	■
 Italy <sup>3</sup>		■				■	■	■		■
 Switzerland						■	■			■
 United Kingdom						■				
<b>Asia</b>										
 China										
 Israel		■				■	■			■
 Japan						■				■
 Malaysia		■								
 Saudi Arabia	■	■								
 Singapore	■									
 South Korea		■								
 Vietnam										
<b>Oceania</b>										
 Australia	■	■								

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## Insurance Coverage by Country\* continued

	Prostate cancer	Thyroid nodules	Uterine fibroids	Varicose veins							
<b>North America</b>											
Canada <sup>2</sup>			■								
United States <sup>1</sup>	■		■								
<b>Europe</b>											
Denmark											
France	■										
Germany	■	■ <sup>4</sup>	■	■ <sup>4</sup>							
Italy <sup>3</sup>			■								
Switzerland											
United Kingdom	■										
<b>Asia</b>											
China			■								
Israel			■								
Japan	■										
Malaysia			■								
Saudi Arabia	■		■								
Singapore	■										
South Korea	■		■								
Vietnam			■								
<b>Oceania</b>											
Australia	■		■								

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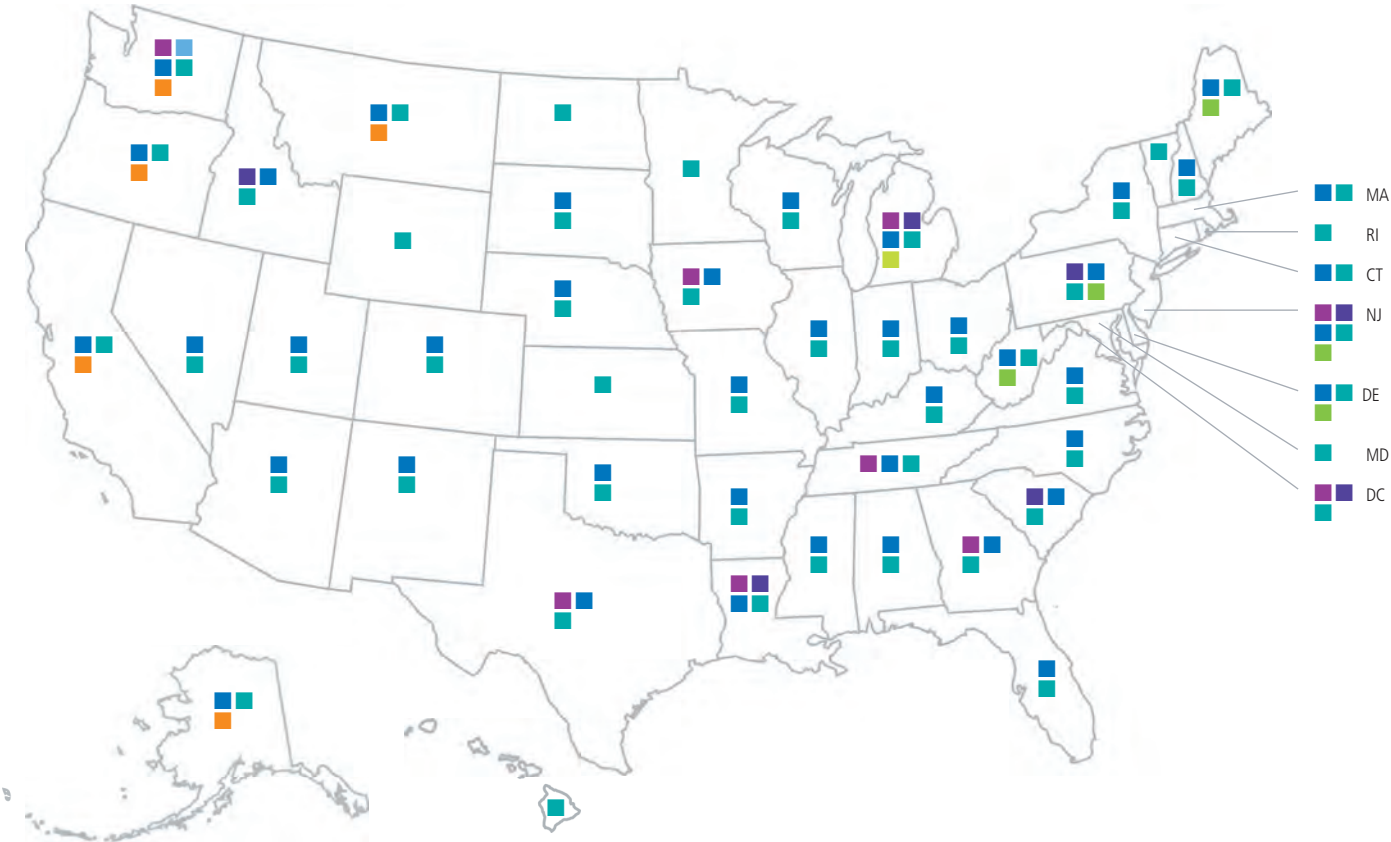
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# REIMBURSEMENT

## Insurance Coverage in the United States\*

### Bone metastases | Pain palliation



### Bone metastases | Pain palliation

#### Private carriers

- Amerigroup Healthcare  
DC, GA, IA, LA, MI, NJ, TN, TX, WA
- AmeriHealth  
DC, ID, LA, MI, NJ, PA, SC
- Asuris Northwest Health  
WA
- Blue Cross Blue Shield  
AK, AL, AR, AZ, CA, CO, CT, DE, FL, GA, IA, ID, IL, IN, KY, LA, MA, ME, MI, MO, MS, MT, NC, NE, NH, NJ, NM, NV, NY, OH, OK, OR, PA, SC, SD, TN, TX, UT, VA, WA, WI, WV
- CIGNA  
ALL STATES AND DC
- Geisinger Health Plan  
DE, ME, NJ, PA, WV

- HAP Health Alliance Plan  
MI
- Providence Health Plan  
AK, CA, MT, OR, WA

#### Covered lives

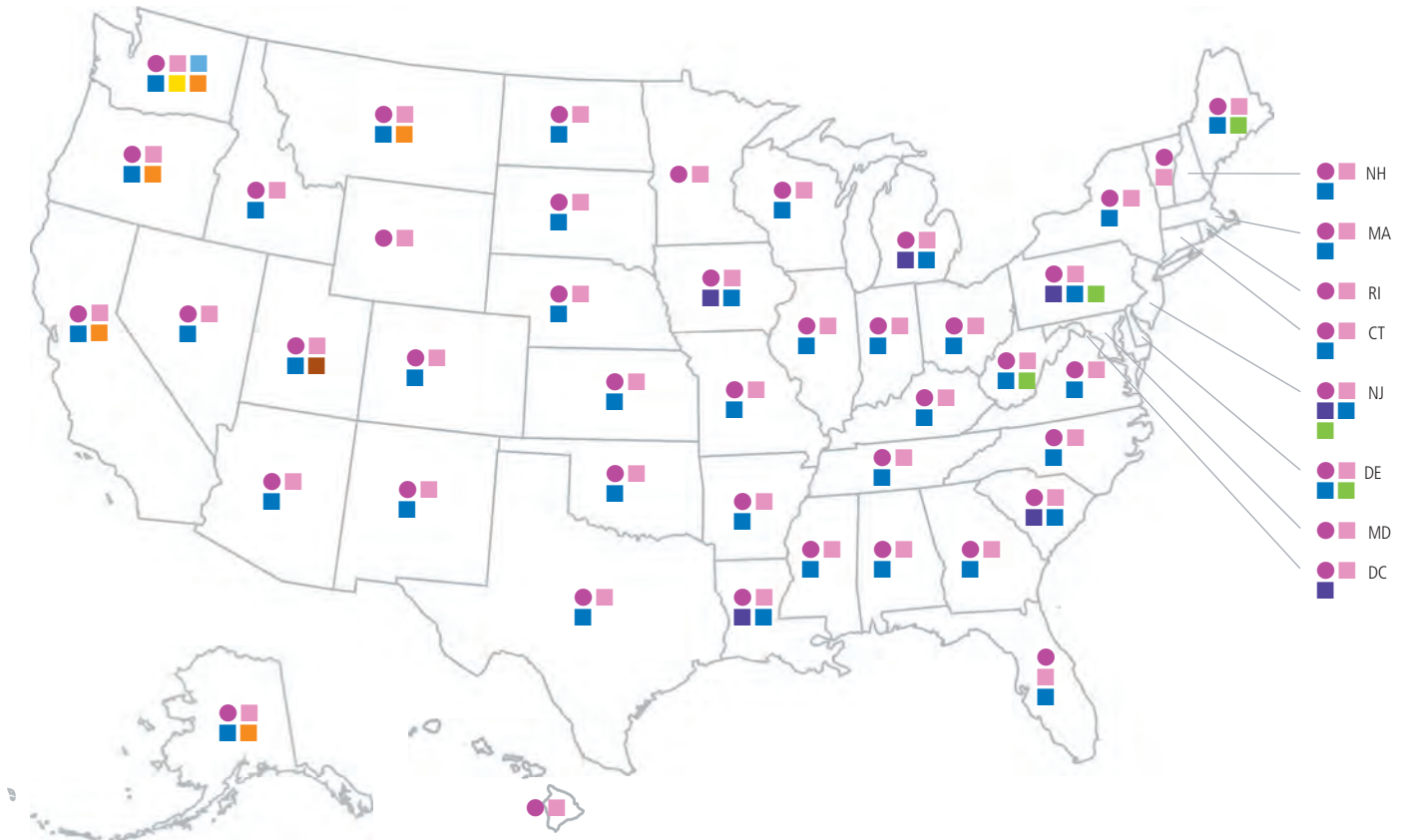
Medicare	—
Private	115.6
	115.6 million

\* All coverage decisions are conditional. The most current policy documents from the individual insurers should be referenced for a complete description.



# Insurance Coverage in the United States\* continued

## Essential tremor



## Essential tremor

### Public carrier

- Medicare  
ALL STATES AND DC

### Private carriers

- Aetna  
ALL STATES AND DC
- AmeriHealth  
DC, IA, LA, MI, NJ, PA, SC
- Asuris Northwest Health  
WA
- Blue Cross Blue Shield  
AK, AL, AR, AZ, CA, CO, CT, DE, FL, GA, IA, ID, IL, IN, KS, KY, LA, MA, ME, MI, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NV, NY, OH, OK, OR, PA, SC, SD, TN, TX, UT, VA, WA, WI, WV
- Geisinger Health Plan  
DE, ME, NJ, PA, WV

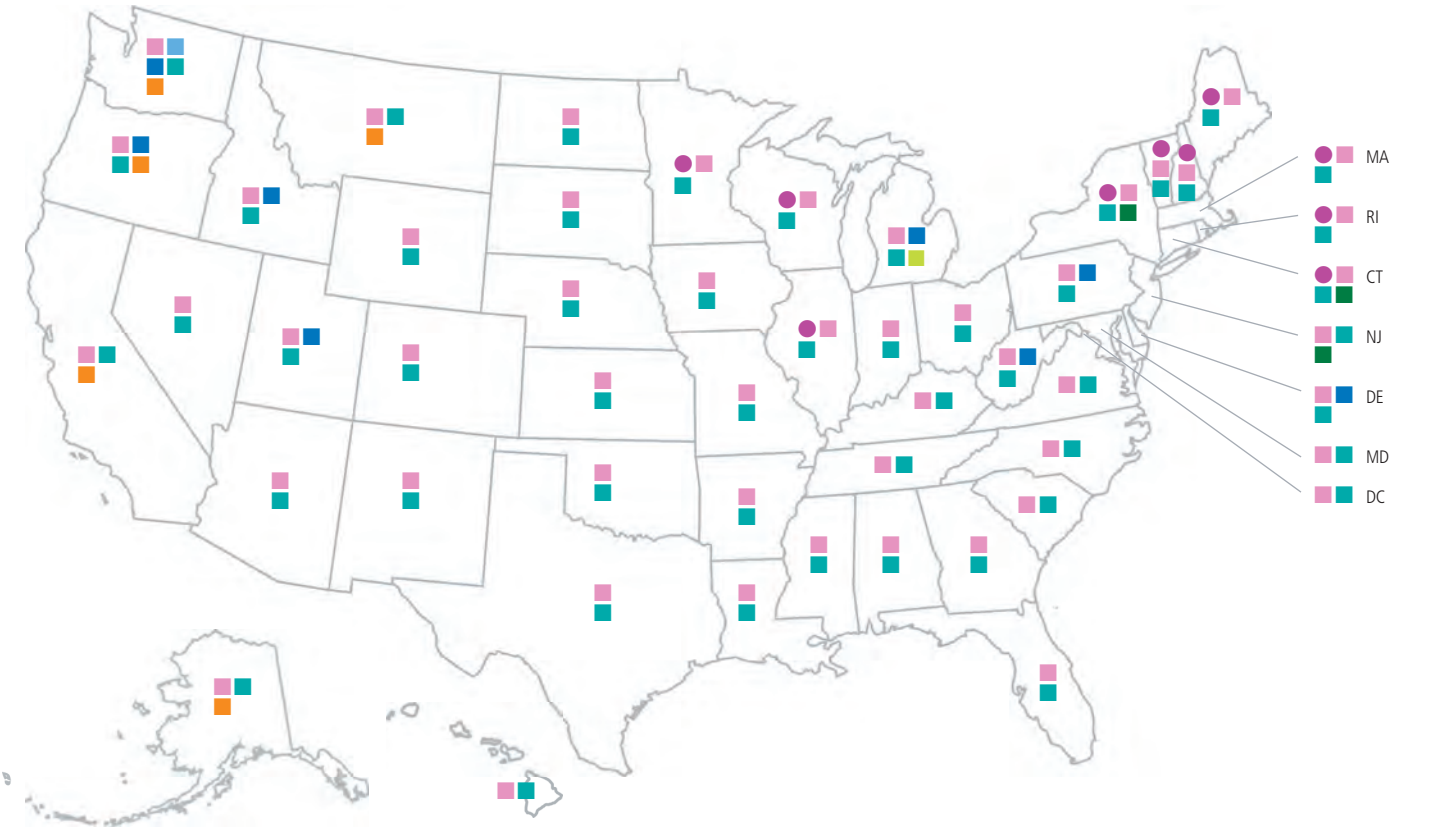
- Lifewise  
WA
- Providence Health Plan  
AK, CA, MT, OR, WA
- University of Utah Health Plans  
UT

Covered lives	Medicare	63.0
	Private	121.6
		184.6 million

\* All coverage decisions are conditional. The most current policy documents from the individual insurers should be referenced for a complete description.

Insurance Coverage in the United States\* continued

Prostate cancer | Salvage therapy<sup>1</sup>



Prostate cancer | Salvage therapy<sup>1</sup>

- Public carrier**

  - Medicare  
CT, IL, MA, ME, MN, NH, NY, RI, VT, WI
- Private carriers**

  - Aetna  
ALL STATES AND DC
  - Asuris Northwest Health  
WA
  - Blue Cross Blue Shield  
DE, ID, MI, OR, PA, RI, UT, WA, WV
  - CIGNA  
ALL STATES AND DC
  - Emblem Health  
CT, NJ, NY

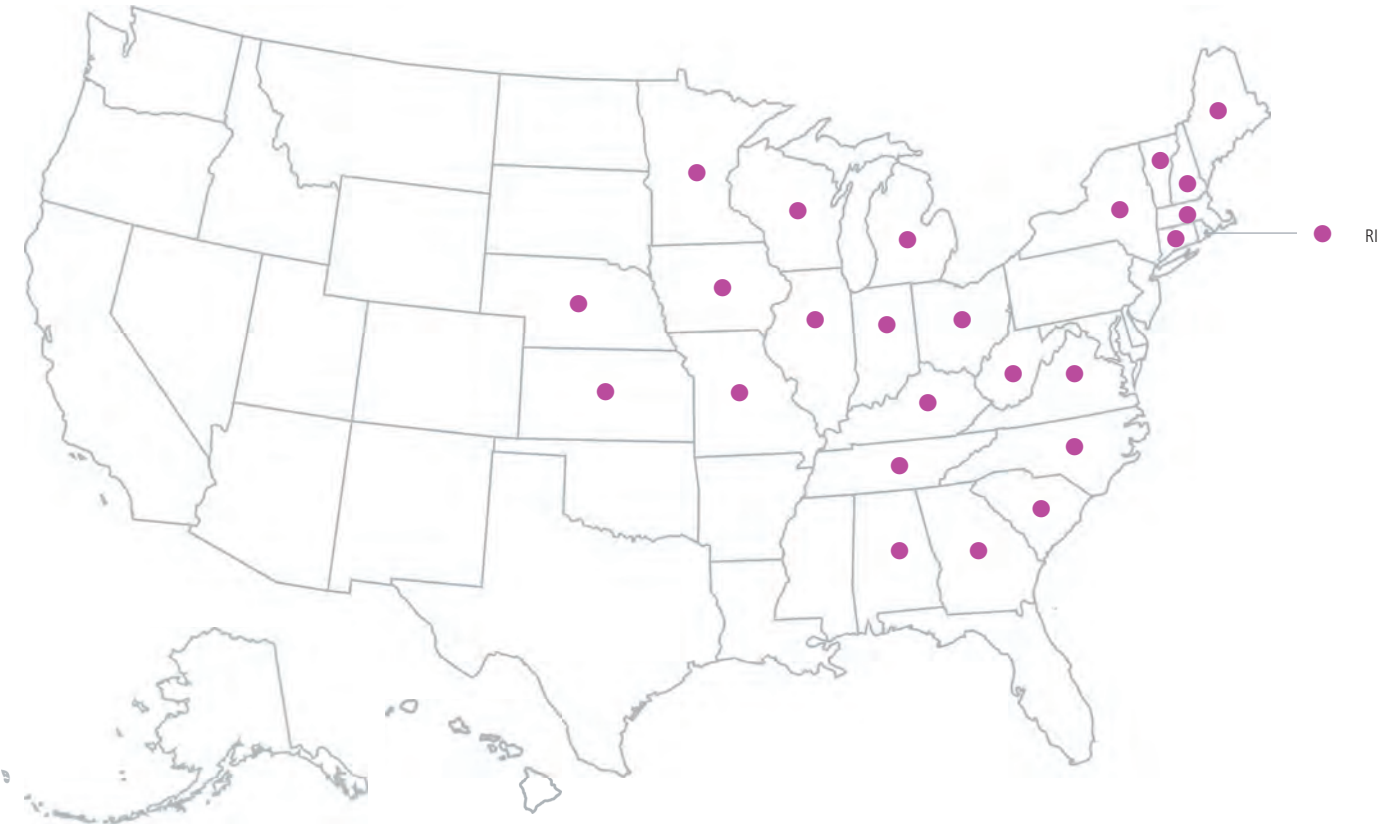
- HAP Health Alliance Plan  
MI
- Providence Health Plan  
AK, CA, MT, OR, WA

Covered lives	Medicare	11.5
	Private	53.0
		64.5 million

\* All coverage decisions are conditional. The most current policy documents from the individual insurers should be referenced for a complete description.  
<sup>1</sup> Local treatment for recurrent prostate cancer following radiation therapy

Insurance Coverage in the United States\* continued

Parkinson’s disease, tremor



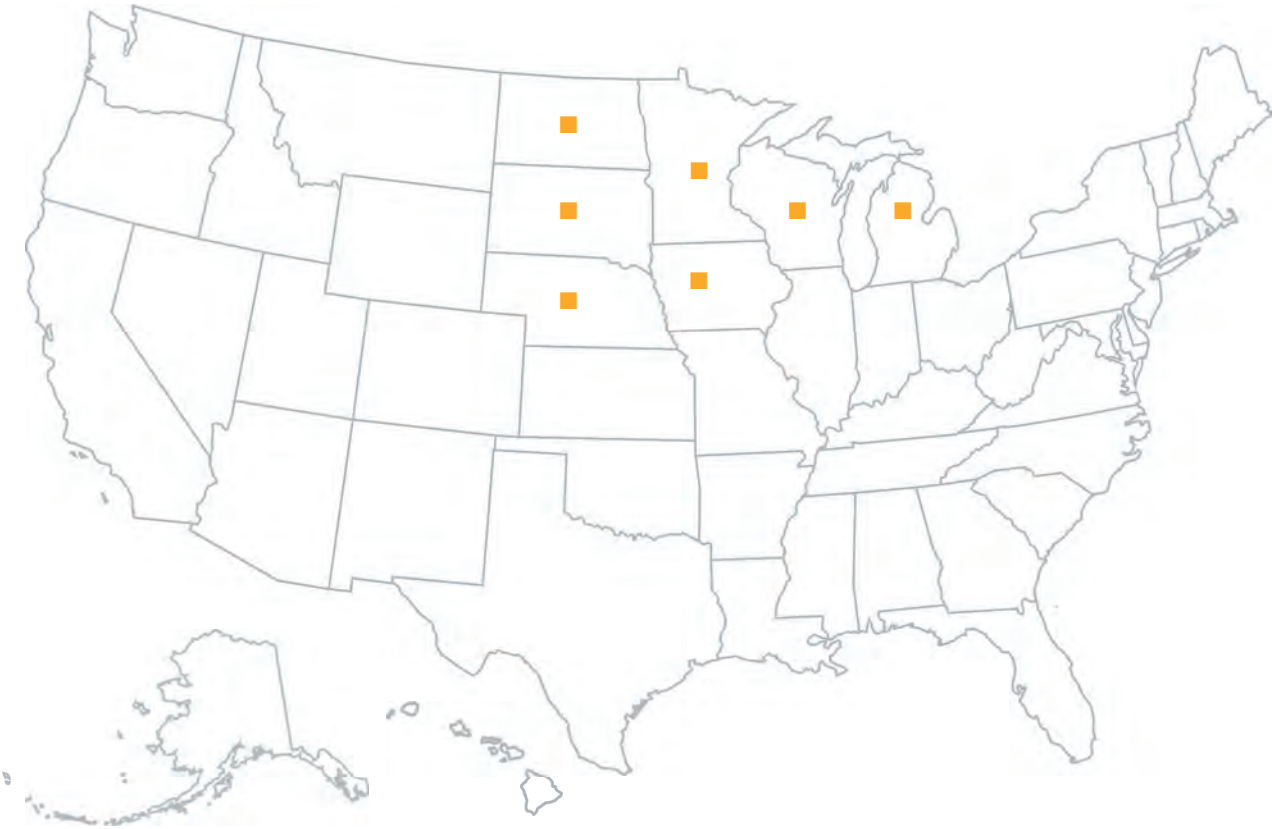
Parkinson’s disease, tremor

Public carrier	● Medicare	
	AL, CT, GA, IA, IL, IN, KS, KY, MA, ME, MI, MN, MO, NE, NC, NH, NY, OH, RI, SC, TN, VA, VT, WI, WV	
Covered lives	Medicare	30.7
	Private	—
		30.7 million

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Insurance Coverage in the United States\* continued

Uterine fibroids



Uterine fibroids

Private carrier    Preferred One  
IA, MI, MN, NE, ND, SD, WI

Covered lives	Medicare	—
	Private	0.37
		0.37 million

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