

Focused Ultrasound Case Study

FUS and Reimbursement in Italy



The Italian National Health Service (NHS)

The Italian constitution defines healthcare as a fundamental right and guarantees free medical care to the population. The National Health Service (NHS) is currently organized on three institutional levels: central, regional, and local. The Ministry of Health of the central government coordinates the NHS and ensures equal access to healthcare. The operational responsibility of healthcare lies with each of the 20 autonomous Regions. The State-Regions agreement defines the economic resources to be provided to the Regions by the central government and the Essential Levels of Assistance (LEAs) that the NHS is required to provide to all citizens. The NHS is funded through general taxation.

The Regions have great autonomy in designing their regional healthcare system and have the ability to provide additional services and treatments financed with their own

resources. They define their local operational units—the Aziende Sanitarie Locali (ASLs)—as well as which hospitals are part of an ASL, and which are autonomous organizations (Aziende Ospedaliere—AOs), independent from the ASLs.

Highly specialized services such as focused ultrasound are provided by University Hospitals and Istituti di Ricovero e Cura a Carattere Scientifico (Scientific Institutes for Hospitalization and Treatment, IRCCSs). The University Hospitals are part of the university structures and are independent of the local ASL. The IRCCSs are hospitals of excellence with strong research focus, predominantly clinical and translational research. IRCCSs have one or more areas of specialization, making them distinct from general hospitals and attractive to patients.

Reimbursement of FUS Procedures



With healthcare in Italy governed by the **20 autonomous regions**, reimbursement is largely specific to the regions where respective technology is available.

The Italian reimbursement system

The Italian NHS guarantees the Essential Levels of Assistance (LEAs) that every citizen can access across the country. They are defined and covered by the central government. Regions also can add further levels of assistance in response to internal demand. Accordingly, there are national tariffs established by the Ministry of Health and regional tariffs established by the Regional Healthcare Departments. The latter may implement an additional reimbursement for higher costs associated with the use of specific medical devices that are more expensive than the basic tariff.

The codification system for hospital care is the International Classification of Diseases ICD-9-CM for the main diagnosis and a catalog of codes for procedures. Assigned codes are collated and linked to a Diagnostic-Related Group (DRG), in addition to the related reimbursement tariff for the procedure or treatment.

Currently, there is no LEA for any focused ultrasound procedure on the national level, so reimbursement for FUS procedures is determined and implemented on the respective regional levels of FUS sites.

Introduction of technological innovation in the Italian NHS

Health Technology Assessments (HTAs) have become a crucial step in obtaining reimbursement from the Regions. There is a formal National HTA Program that identifies and assesses medical technology; it is managed and organized by Agenzia Nazionale per i Servizi Sanitari Regionali (AGENAS), a National Agency representing the Regional Healthcare Systems. However, new emerging technologies like FUS are rarely recognized as a necessary service on the national level; usually, their value needs to be demonstrated in more than one institution at the regional level first.



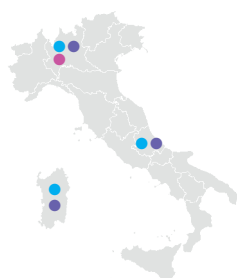
Neurological

Neurological disorders

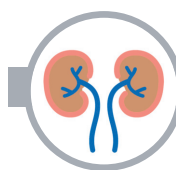
Reimbursement for essential tremor and Parkinson's disease, tremor-dominant is established in the regions where the technology is available: Abruzzo, Lombardia, and Sicilia.

Reimbursement for neuropathic pain has been established in the region of Besta through individual agreements between sites and region administration.

In most regions, surgery for a neurological disorder is equated to a craniotomy, and the application of the stereotactic helmet also triggers the DRG for a craniotomy, with reimbursement of around €10,000–€12,000 per procedure.



- Essential tremor
- Parkinson's disease, tremor dominant
- Neuropathic pain



Urological

Prostate cancer

With 22 centers treating prostate cancer in Italy, there are some coverage and reimbursement agreements in place.

On average, hospitals receive €4,150 for the treatment, including 2 nights and value added tax (VAT).



22
centers

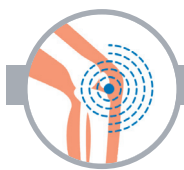
The autonomous Regions have each implemented their own HTA programs, with various degrees of sophistication and respective agencies and authorities.

The regions of Abruzzo, Lombardia, Sicilia, and Veneto largely follow the structure of the National HTA Program in the assessment of new technologies, with regional agencies and their responsibilities in the process clearly identified. In Emilia-Romagna, the requirements for a new treatment to be recognized are strong scientific evidence and long-term economic viability. In this case, the presence of an HTA is critical, even though there are currently no regional guidelines on how to produce a structured, specific HTA. Other regions have different types of technology evaluation and decision-making paths, which can vary for different types of technology and are not necessarily well documented.

The case of Fondazione IRCCS Istituto Neurologico Carlo Besta, Milan

The Besta Institute's purchase of the MR-guided FUS (MRgFUS) ExAblate 4000 system was linked to the construction of a new operating theater and the purchase of a new MRI. In 2015, the Institute received an earmarked donation to purchase the FUS device. The Region was in favor of the introduction because local patients were currently traveling to Palermo, Sicilia for essential tremor treatments. The donation received, and the competing presence of the MRgFUS in Sicilia, prompted the Region to update the LEAs and permit the treatment at IRCCS C. Besta.

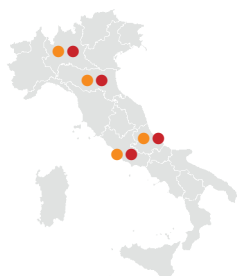
To include the procedure in the LEAs and to establish reimbursement, the Region requested a study demonstrating the safety and effectiveness of the treatment. This information was included in the HTA together with an economic impact analysis.



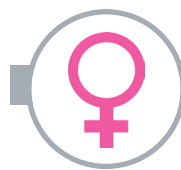
Musculoskeletal

Bone metastases, osteoid osteoma

Reimbursement for bone metastases and osteoid osteoma is established in the regions of Abruzzo, Emilia Romagna, Lazio, and Lombardia by individual agreements between sites and region administration.



● Bone metastases
● Osteoid osteoma



Women's health

Uterine fibroids, body applications

Reimbursement for uterine fibroids and other body applications is available in Abruzzo, Basilicata, Emilia Romagna, Lazio, Le Marche, Lombardia, Tuscany, and Umbria, triggered by the availability of the technology and an HTA.

The procedure is reimbursed at €3,000 – €6,000.



● Uterine fibroids

The Region recognized the tariff differentiation in the DRG 008, “Surgeries on peripheral and cranial nerves and other nervous system surgeries without CC,” with a reimbursement rate of €11,799. The DRG has been attributed to Besta because of the competencies of its staff and the HTA report.

IRCCS Besta created an Alert HTA on MRgFUS, consisting primarily of an analysis of the scientific literature with the conclusions that the MRgFUS treatment can be considered an effective and safe treatment for unilateral essential tremor unresponsive to drug therapy. Therefore, MRgFUS can be considered a new option for patients for whom there are contraindications to treatment with deep brain stimulation

(DBS) or radiosurgery, and a valid alternative for patients who are candidates for these treatments. The estimated cost of a procedure performed at IRCCS C. Besta is €14,583.

To date, DBS is no longer performed at IRCCS C. Besta and has been replaced by FUS treatments.

2022 State of the Field

This case study appears in the *2022 State of the Field Report* which is available on the Foundation’s website.

The report documents the progress that is only possible through the hard work, time, and resources of everyone in our community.

