

JUDICIALIZATION OF TECHNOLOGIES IN SUPPLEMENTARY HEALTH STF'S ADI NO. 7265



BACKGROUND

The Direct Action for Declaration of Unconstitutionality No. 7265 (ADI 7265), filed by the National Union of Self-Management Institutions in Health (UNIDAS), addressed the constitutionality of two provisions of Law No. 14,454/22, which amended the Health Plans Law to establish criteria for the coverage of exams and treatments not yet incorporated into the basic list of procedures of the National Supplementary Health Agency (ANS):

- ✓ The ANS list, as updated by the Agency with each new incorporation, constitutes the basic reference for coverage by health plans (§ 12 of Article 10 of the Health Plans Law); or
- ✓ Coverage of technologies, even if not included in the ANS list, must be authorized by the health plan, provided that: (i) there is proof of effectiveness, based on scientific evidence and a therapeutic plan; or (ii) there is a recommendation for incorporation into the Unified Health System (SUS) by the National Commission for the Incorporation of Technologies (Conitec), or by at least one internationally renowned technology assessment body, provided that the technology is also approved for use in its country of origin (§ 13 of Article 10 of the Health Plans Law).



WHY IS THIS RULING IMPORTANT?

The Federal Supreme Court's (STF) interpretation will impact access to various health technologies, including medicines, medical devices, treatments, exams, surgeries, and OPMEs (Orthotics, Prostheses, and Special Materials), among others. In addition, the STF aims to resolve the debate regarding whether the ANS list is illustrative or exhaustive.

JUN 8,
2022

THE SUPERIOR COURT OF JUSTICE (STJ) DECIDED FOR THE EXHAUSTIVENESS OF THE ANS LIST, WITH EXCEPTIONS (ERESP NO. 1,886,929/SP AND 1,889,929/SP)

SEP 21,
2022

LAW NO. 14,454/22 PUBLICATION

NOV 4,
2022

ADI NO. 7265 FILING

APR 10,
2025

ADI NO. 7265 PUBLIC HEARING

SEP 18,
2025

STF RULLING OF ADI NO. 7265

MAJORITY OPINION

On September 18, 2025, the STF ruled that the provisions of Law No. 14,454/22 were partially constitutional, adopting the opinion of the reporting Justice Luís Roberto Barroso.

The legal requirement for coverage of treatments or procedures not included in the ANS list is constitutional, provided that the technical and legal parameters set forth below are satisfied.

Coverage of treatments or procedures not provided for in the ANS list **must be authorized by the health plan**, provided that the following 5 requirements are cumulatively met:

1. prescription by a physician or dentist;
2. absence of express denial or pending evaluation by the ANS regarding the proposal for ANS list update;
3. absence of an appropriate therapeutic alternative for the patient's condition within the ANS list;
4. Proof of efficacy and safety of the treatment, which must consider evidence-based medicine or Health Technology Assessment (ATS) standards and necessarily be supported by high-level scientific evidence (randomized clinical trials, systematic reviews, or meta-analyses); and
5. existence of marketing authorization with the National Health Surveillance Agency (Anvisa), when applicable.

Subject to having the judicial decision null and void, judges must adopt the following measures when ruling in lawsuits involving technologies not included in the ANS list:

- a. Verify whether there is proof of a prior request submitted to the health plan, as well as proof of denial, unreasonable delay, or omission by the health plan in authorizing the non-incorporated treatment;
- b. Analyze the administrative act that did not incorporate the technology, considering the specific circumstances of the case, without delving into the technical-administrative merits;
- c. Assess whether the 5 requirements set forth above are met, after prior consultation with Natjus, whenever available, or with entities or individuals possessing technical expertise. The decision must not be based solely on a prescription, report, or medical document submitted by the party. For reference, Natjus is a technical body established on a state or federal court level, which must support judges in assessing clinical or technical matters arising in lawsuits involving health care assistance; and
- d. If the request is judicially approved, notify the ANS so that it may assess the possibility of including the treatment in the list of mandatory coverage.

DISSENTING OPINION

Justice Flávio Dino dissented from the vote proposed by Justice Barroso, defending:

- ✓ The need for technical deference to the ANS and the existing normative acts;
- ✓ That the Health Plans Law itself provides for coverage exceptions to ANS's basic list; and
- ✓ That the creation of a ruling opinion with interpretation criteria would create undue interference in the sphere of competence of the regulatory agency.



FINAL SCORE

✓ Winning Opinion	✗ Dissenting Opinion
✓ JUSTICE LUÍS ROBERTO BARROSO	✗ JUSTICE FLÁVIO DINO
✓ JUSTICE NUNES MARQUES	✗ JUSTICE EDSON FACHIN
✓ JUSTICE CRISTIANO ZANIN	✗ JUSTICE ALEXANDRE DE MORAES
✓ JUSTICE ANDRÉ MENDONÇA	✗ JUSTICE CÁRMEN LÚCIA
✓ JUSTICE LUIZ FUX	
✓ JUSTICE DIAS TOFFOLI	
✓ JUSTICE GILMAR MENDES	

In September 2024, the Supreme Court ruled in a similar way on criteria for the judicial supply of medicines in the SUS – without mentioning other health technologies. According to Topics 6 and 1234, ruled by the Supreme Court, a public entity is required to provide medicines non-incorporated by Conitec into the SUS, provided that 6 requirements are cumulatively met:



1. Existence of an administrative refusal to supply the medicine;
2. Illegality in Conitec's decision to not incorporate the medicine, absence of a request for incorporation, or delay in its assessment;
3. Unfeasibility of replacing the medicine with another one existent in Conitec's clinical protocols and therapeutic guidelines;
4. Proof of the medicine's efficacy, accuracy, effectiveness, and safety, necessarily supported by randomized clinical trials and systematic review or meta-analysis;
5. Clinical indispensability of the treatment, proven by a substantiated medical report, which also describes treatments already performed; and
6. Patient's financial inability to bear the cost of the medicine.



POINTS OF ATTENTION

- ⚠ Upon publication of the votes and respective ruling, the parties may file a motion for clarification.
- ⚠ ADI No. 7265 ruling reflects the STF's interpretation regarding the provision of technologies not incorporated into the ANS list. However, it did not result in a binding precedent, as occurred in Topics 6 and 1234.
- ⚠ Mandatory prior consultation with Natjus before adjudicating judicial requests for supplies may overburden these technical bodies.
- ⚠ The ANS list is updated on a continuous basis. Upon submission of a request for incorporation, the Agency has up to 270 days to evaluate the request, after which automatic incorporation will occur unless and until the ANS issues an effective decision.
- ⚠ Need for integration with the national platform for the judicialization of medicines, created under Topic 1234. The system prototype, which is expected to be presented by December 2024, is currently in the testing phase.



WORTH FOLLOWING UP

Developments related to Topics 6 and 1234 of the STF, which address the provision of medicines not incorporated into the SUS' list.

Lawsuit No. 5037147-80.2023.4.03.6100/JFSP: discusses the legality of ANS Technical note 3/23, which addresses with the incorporation of advanced therapy medicinal products in the ANS' list.

Bill No. 4,741/21 by Deputy Luizinho: proposes expanding the ANS's authority to address the incorporation, exclusion, and modification of health technologies, as well as the development and review of clinical protocols and therapeutic guidelines, leveraging the expertise developed by Conitec.

Complementary Bill No. 149/24 by Senator Romário: sets forth requirements for the provision of medicines that have not been incorporated into SUS normative acts or registered with Anvisa and establishes criteria for recognizing the solidarity obligations of federal entities in promoting the right to health.

Complementary Bill No. 168/24 by Deputy Rosângela Moro: discusses requirements for the granting of medicines not incorporated into SUS normative acts.

Bill No. 4,202/24 by Deputy Juninho do Pneu: discusses the judicial granting of medicines not incorporated into the SUS in specific and urgent cases.

COUNT ON MACHADO MEYER

Federal and state courts are already applying recent STF interpretations to grant, deny, or suspend coverage of health technologies. Our Life Sciences & Healthcare expertise uniquely positions us to help companies across the sector (pharmaceuticals, biotechnology, advanced therapies, medical devices, diagnostics, among others) assess strategies and options for registering and incorporating technologies into Brazil's SUS and the supplementary health system.

GET IN TOUCH



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