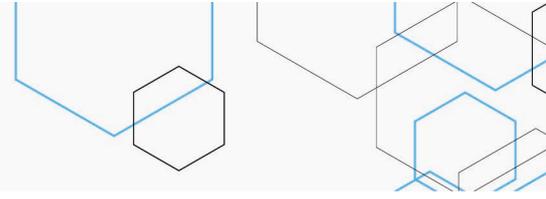


**Inclusion of levothyroxine sodium
presentations of 12.5 and 37.5 mcg
for treatment of congenital
hypothyroidism**



Technology: Levothyroxine sodium.

Indication: Congenital hypothyroidism.

Applicant: Secretariat of Science, Technology and Strategic Inputs (Ministry of Health of Brazil).

Background: Congenital Hypothyroidism (CH) is the most common congenital endocrine disorder and the leading preventable cause of intellectual disability in the world. In Brazil, the incidence of CH is one per 2,595 to 4,795 live births. The prognosis depends fundamentally on the time of initiation of treatment, the severity of hypothyroidism, and maintenance of hormone levels within the normal range. The treatment involves with levothyroxine and should be started as soon as possible to prevent impairment of mental development and growth in the child.

Justification of the request: The levothyroxine sodium presentations which are included in the Brazilian National Relation of Essential Medicines (Rename, in Portuguese) and recommended in the Clinical Protocol and Therapeutic Guidelines for Congenital Hypothyroidism (CH) are tablets of 25, 50 and 100 mcg. The dosage should be adjusted on a regular basis according to the child's growth and the levels of TSH and total or free T4. Therefore, the use of intermediate presentations of 12.5 mcg and 37.5 mcg reduces the need to split tablets to obtain the required dosage and the appropriate dose adjustment, as well as minimizes administration errors and wastage of tablets. In a scope meeting to review the Clinical Protocol and Therapeutic Guidelines for CH, held on September 11th, 2019, with the participation of methodologists, expert endocrinologists, and members of the Department of Management and Incorporation of Technologies and Innovation in Health (DGITIS) of the Secretariat of Science, Technology and Strategic Inputs (SCTIE), it was suggested that the incorporation of levothyroxine sodium presentations of 12.5 and 37.5 mcg for the treatment of patients with CH should be taken into consideration.

Final Deliberation: The CONITEC's members present at the 88th Ordinary Meeting, on July 8th, 2020, unanimously decided to recommend the incorporation of levothyroxine sodium 12.5 and 37.5 mcg for the treatment of congenital hypothyroidism in the scope of the Brazilian Public Health System (SUS). The Deliberation Record No. 536/2020 was signed.

Decision: To incorporate levothyroxine sodium 12.5 and 37.5 mcg for the treatment of patients with congenital hypothyroidism, according to the Clinical Protocol and Therapeutic Guidelines of the Ministry of Health of Brazil, in the scope of SUS, according to Ordinance No. 38, published in the Official Gazette of the Federal Executive No. 181, Section 1, page 235, on September 21st, 2020.

