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State-Recommended Guidelines for Follow-Up of a Positive Newborn Screen for Primary Congenital Hypothyroidism

These are broad guidelines developed by a committee of pediatric endocrinologists in collaboration with the California Newborn Screening Program. There may be circumstances in individual cases which supersede these guidelines. Please consult with a pediatric endocrinologist in your area for guidance.

The California Newborn Screening Program **strongly** recommends that babies with positive newborn screening tests for primary congenital hypothyroidism (CH) be referred to a CCS-approved pediatric endocrinology center (see attached list) or a CCS-paneled pediatric endocrinologist for diagnostic evaluation and initiation of treatment. The Newborn Screening Area Service Center staff will assist you in obtaining a referral. CCS will cover diagnostic services in the absence of insurance.

Babies with CH may not exhibit signs and symptoms at birth. Nevertheless, examine these infants for signs of hypothyroidism, *i.e.*, constipation, lethargy, jaundice, hypothermia, *etc.*, and note history of any maternal thyroid disease and/or use of medications that could cause transient hypothyroidism in the newborn (*e.g.*, propylthiouracil [PTU], methimazole [Tapazole], or any other with high iodine content). Initiation of treatment is determined by laboratory values as per the following recommendations:

- **If the newborn screen TSH is >40 micro international units/milliliter ($\mu\text{IU}/\text{mL}$):**

Obtain a serum TSH and either a free T4 or total T4 at a lab that can assure a turn-around of 24 hours or less and initiate treatment as soon as the blood sample is drawn. See below for recommended levo-thyroxine dosage. Refer baby to a pediatric endocrinologist to be seen promptly.

- **If the newborn screen TSH is 29-40 $\mu\text{IU}/\text{mL}$:**

Obtain a serum TSH and either a free T4 or total T4 at a laboratory that can assure a turnaround of 24 hours or less. Do not start levo-thyroxine before confirmatory results are received.

Interpret blood test results as follows:

- a. If collected in the first two weeks of life and the TSH value is $\leq 10 \mu\text{IU}/\text{mL}$, the result is considered normal and the case can be resolved as negative.
- b. If the TSH value is $\geq 10 \mu\text{IU}/\text{mL}$ but $\leq 40 \mu\text{IU}/\text{mL}$, repeat the free T4/total T4 and TSH, and refer the baby to a pediatric endocrinologist who will interpret TSH result in light of the total T4/free T4 value to determine whether or not treatment should be initiated.

- c. If the TSH value is $> 40 \mu\text{IU/mL}$, initiate levo-thyroxine treatment immediately and promptly refer the baby to a pediatric endocrinologist.

RECOMMENDED TREATMENT

American Academy of Pediatrics (AAP) treatment guidelines* state that **treatment (levo-thyroxine) should be started within the first 2 weeks of life to allow for optimal cognitive development.**

Levoxyl is the recommended formulation as it dissolves faster than other brands of thyroxine.

RECOMMENDED ORAL LEVO-THYROXINE DOSAGE FOR TERM AND PRETERM BABIES:

10-15 micrograms/kg/day

Baby's Weight	Levo-thyroxine Dose
2000-2499 grams	25 micrograms daily
2500-3999 grams	37.5 micrograms daily
4000 grams or more	50 micrograms daily

Consult with a pediatric endocrinologist for the recommended dosage for preterm infants (< 2000 g) or for intravenous administration.

- **Have the pharmacy dispense the drug as tablets, as it is unstable in liquid (suspension) form. DO NOT USE ANY COMPOUNDED LIQUID FORMULATION.**
- Tablets should be crushed and administered in a very small amount of water, breast milk, or formula that does not contain soy or iron. The mixture, given as a single daily dose, should be placed directly into the baby's mouth via a spoon. Ideally, the medication should be given 30 minutes prior to a feeding.
- Subsequent dosage may need to be adjusted based upon lab results.
- Refer to AAP guidelines* for recommended monitoring schedule.

Reference:

*American Academy of Pediatrics, Rose SR;Section on Endocrinology and Committee on Genetics, American Thyroid Association, Brown RS; Public Health Committee, Lawson Wilkins Pediatric Endocrine Society, Foley T, Kaplowitz PB, Kaye CI, Sundarajan S, Varma SK. Update of newborn screening and therapy for congenital hypothyroidism. Pediatrics 2006 June;117(6): 2290-2303.

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