

SPARC
Crisis Intervention Services

1. Is this a “Rate Change” or a “Method Change”? Method Change – adding new test
 - 1b. Is this change an increase, decrease, or no impact? Increase
2. Presentation of issue – Why is change being made? The Oklahoma State Department of Health (OSDH) has recently (February 2015) added a new test to the existing state-mandated panel for newborn screening (NBS). This test, which screens for Severe Combined Immunodeficiency Disorder (SCID), was approved as part of the national Recommended Uniform Screening Panel (RUSP) for newborn testing, which includes 31 core disorders and 26 secondary disorders, in May 2010. The OSDH NBS Program has systematically adopted all testing reflected in the nationally-recognized RUSP. SCID includes more than 10 genetic disorders characterized by profound defects in both cellular immunity and specific antibody production, and is estimated to occur in about 1/33,000 births. Early identification of the asymptomatic SCID infant during the first few weeks of life is essential for successful treatment, which generally involves allogeneic hematopoietic stem cell transplantation. SCID infants who are treated early have almost 10-fold lower total clinical care costs compared with those treated later. If undiagnosed, SCID infants usually die from severe infections with the first year of life. Unfortunately, while SCID is potentially treatable, it is infrequently recognized prior to the onset of devastating infections.

This test will also detect clinically important, non-SCID T-cell-related lymphocyte deficiencies in newborns, which can also be associated with serious morbidities in early childhood. Currently more than half of the babies born in the US are screened for SCID. SCID testing in newborns involves real-time PCR – a technology that is currently not part of other NBS testing – to amplify T-cell receptor excision circles (TRECs). The OSDH Public Health Laboratory (PHL) secured funding from the CDC in 2013 to develop the capacity to offer SCID screening of newborns in Oklahoma; these funds were used to purchase equipment, reagents and consumables for test validation and to hire testing personnel. Following, comprehensive test validation, the OSDH PHL implemented routine, population-based SCID screening of newborns in February 2015. The CDC funds were not intended, and are insufficient, to sustain any long term testing; therefore, OSDH is requesting a charge of \$6 to be added to the current fee in order to off-set the added costs incurred in performing SCID screening. These costs included those associated with laboratory analysis of dried blood spot specimens and follow-up triage of presumptive cases by Screening and Special Services.
3. Current methodology and/or rate structure. This is a new test that has been recently added to the NBS testing panel in Oklahoma; currently, OSDH is not charging nor getting reimbursed for this test.
4. New methodology or rate. The CPT code applicable to SCID testing is 81479, Unlisted Molecular Pathology Procedure.

Various cost analyses have been performed by facilities in the USA and elsewhere that have implemented SCID newborn screening. Estimates generally range from \$5 to \$17.00 per test:

 - Florida Department of health estimates \$17 per test (<http://www.scidangelsforlife.com/wp-content/uploads/2013/04/SCID-Brochure-v4-1.pdf>)
 - Maryland Department of Health and Mental Hygiene estimates \$6.29 per test

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- (http://dlslibrary.state.md.us/publications/JCR/2012/2012_57-58.pdf)
- Missouri Department of Health estimates \$6 per test (<http://www.moga.mo.gov/oversight/OVER12/fispdf/5346-01N.ORG.PDF>)
 - Washington DC estimates \$5 per test (<http://idfscidnewbornscreening.org/washington-dc-and-new-jersey-move-toward-scid-newborn-screening/>)
 - Washington State Public Health Lab estimates \$8.10 per test (<http://sboh.wa.gov/Portals/7/Doc/Meetings/2013/10-09/WSBOH-10-09-13-Tab09d.pdf>)
 - Wisconsin Public Health Lab estimates \$6 per test (<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2846807/>)
 - Jeffery Modell Foundation estimates \$4.25 per test (<http://www.immunologia.org/Upload/Documents/5/4/543.pdf>)
 - United Kingdom White Paper estimates \$13.20 per test (authors conclude that estimate is generalizable to other health care systems) (<https://keechanphd.files.wordpress.com/2012/08/kee-chan-cost-effectiveness-of-newborn-screening-for-scid.pdf>)
 - France White Paper estimates \$4.70-\$6.80 ([http://www.iacionline.org/article/S0091-6749\(15\)00189-X/abstract](http://www.iacionline.org/article/S0091-6749(15)00189-X/abstract))
 - European White Paper estimates \$4.22 per test (<http://www.ipopi.org/uploads/NBS%20SCID%20White%20Paper%20FINAL%20designed.pdf>)

McGhee et al (2005) performed a comprehensive cost-effectiveness evaluation of SCID screening and concluded that the average cost of performing SCID is approximately \$5, and that there would be an 86% likelihood of SCID screening being cost-effective even at an upper threshold of approximately \$15 (McGhee SA, Stiehm ER, Cowan M, Krogstad P, McCabe ER. Two-tiered universal newborn screening strategy for severe combined immunodeficiency. *Mol Genet Metab.* 2005;86(4):427–430 [http://www.jpeds.com/article/S0022-3476\(05\)00492-0/abstract](http://www.jpeds.com/article/S0022-3476(05)00492-0/abstract)).

Variation in cost estimates may be attributed to differences in methodology, technologies, test volumes, salaries, subsidies, etc.

In review of charges for SCID newborn screening in the states of Arizona, Washington and Florida prompted the Oklahoma State Department of Health Board of Health to approve a rate increase in the NBS fee of \$6.

5. Budget estimate. Based on the number of Medicaid claims in the past State Fiscal Year, it is estimated that the increased cost would be approximately \$179,000.00 per SFY for Medicaid claims.
6. Agency estimated impact on access to care. The OSDH PHL is currently providing population SCID screening at no cost and receives no specific reimbursement for this test. However, the long term sustainability of testing is dependent upon being able to increase the NBS fee by \$6. The benefit to cost ratio for providing SCID testing has been estimated at 4.23, indicating a substantial cost saving to the overall healthcare system by offering SCID screening for newborns.
7. Rate or Method change in the form of a motion. The OSDH proposes that the State Plan Amendment Rate Committee approve an increase in the rate for newborn screening by \$6 to offset the cost of adding SCID testing to the Oklahoma newborn screening panel.

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8. Effective date of change. 6 months from approval date; this will allow NBS providers to make changes to their billing systems and to assess for potential impact that SCID testing may have upon their budgets.

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