

Mayo Clinic Laboratories and Mayo Clinic

Presenter: Cheryl James

Code (s): 0071U (Reconsideration: Drug Metabolism),

003XM (MAAA),

80XX1, 80XX2, 80XXX, 81XX3, 80XX3, 80XX4, 80XX5, 80XX6, 80XX7, 80XX8,
802XX (Chemistry: Therapeutic Drug Testing)

87635 (Microbiology:Viral)

86769 (Microbiology:Viral)

U003 (Microbiology: Viral)

0071U: CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6) (eg, drug metabolism) gene analysis, full gene sequence

Public Comment	Rationale
81238 (\$600) 81238 F9 (coagulation factor IX) (eg, hemophilia B), full gene sequence	We maintain a crosswalk to F9 gene analysis represents the code most similar in methodology and resources, analyzing a similar number of exons (CYP2D6 = 9 exons, F9 = 8 exons). Current crosswalk to 81405 (\$301.45) results in a lower rate for CYP2D6 full gene sequence analysis compared to targeted sequence analyses, codified by 0072U-0076U (\$450.91). This is not appropriate and inconsistent with CMS precedent in other code families.

003XM: Adrenal cortical tumor, biochemical assay of 25 steroids utilizing 24-hour urine specimen and clinical parameters, prognostic algorithm reported as a clinical risk and integrated clinical-steroid risk for adrenal cortical carcinoma, adenoma, or other adrenal malignancy

Public Comment	Rationale
<p>0003U TIMES 2 (\$950 x 2 = \$1,900) Liver disease, ten biochemical assays (ALT, A2-macroglobulin, apolipoprotein A-1, total bilirubin, GGT, haptoglobin, AST, glucose, total cholesterol and triglycerides) utilizing serum, prognostic algorithm reported as quantitative scores for fibrosis, steatosis and nonalcoholic steatohepatitis (NASH)</p>	<p>Similar methodology (LC-MS/MS High Resolution Accurate Mass).</p> <p>Multiplier of 2 reflects the increased resources required to analyze 25 steroids (vs. 5 proteins) and the inclusion of 6 clinical parameters, taking into account economies of scale</p>

801XX3: Alcohol (ethanol); any specimen except urine and breath, immunoassay (eg, IA, EIA, ELISA, RIA, EMIT, FPIA) and enzymatic methods (eg, alcohol dehydrogenase)

Public Comment	Rationale
83520 (\$17.27) Immunoassay for analyte other than infectious agent antibody or infectious agent antigen; quantitative, not otherwise specified	Similar methodology and resources 82075: Alcohol (ethanol); breath uses different methodology and resources

80XXX: Acetaminophen

80XX1: Salicylate

Public Comment	Rationale
80299 (\$18.64) Quantitation of therapeutic drug, not elsewhere specified	Similar methodology and resources 80299 is the code currently used to report these analytes

80XX2: Amiodarone

80XX5: Flecainide

Public Comment	Rationale
80155 (\$38.57) Caffeine	Similar methodology and resources Used for therapeutic monitoring of antiarrhythmic agents

CMS Annual Lab Meeting (June 22, 2020)
Mayo Clinic (James, Cheryl)

80XX4: Felbamate
802XX: Rufinamide

Public Comment	Rationale
80199 (\$27.11) Tiagabine	Similar methodology and resources Used for treating seizures/epilepsy

80XX7: Leflunomide
80XX8: Methotrexate

Public Comment	Rationale
80230 (\$38.57) Infliximab	Similar methodology and resources Used for inflammatory disorders

80XX6: Itraconazole

Public Comment	Rationale
80187 (\$27.11) Posaconazole	Similar methodology and resources Used for treatment of antifungal infections

80XX3: Carbamazepine 10, 11-Epoxyde

Public Comment	Rationale
80155 (\$38.57) Caffeine	Similar methodology and resources Crosswalk to other Carbamazepine codes (80156 and 80157) is not appropriate, as this assay requires significantly different methodology and resources

87635: Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), amplified probe technique

Public Comment	Rationale
U0003 (\$100) or 87502 (\$95.80) Infectious agent detection by nucleic acid (DNA or RNA); influenza virus, for multiple types or sub-types, includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, first 2 types or sub-types	While the U0003 was administratively priced, the rate represents a close approximation of the lab resources required. If this isn't eligible for crosswalk recommend consideration of 87502 which is a similar methodology and resources. Both tests detect multiple types/sub-types of virus and both are performed by amplified probe technique.

86769: Antibody; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])

Public Comment	Rationale
86794 TIMES 2.5 ($\$16.85 \times 2.5 = \42.13) Antibody; Zika virus, IgM	Similar methodology and resources. Multiplier of 2.5 accounts for the additional costs associated with rapid development to address the public health emergency, added supply expense, additional reporting requirements and the resources required for EUA. Consistent with rate set by MACs for 2020

U0003: Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), amplified probe technique, making use of high throughput technologies as described by CMS-2020-01-R

Public Comment	Rationale
<p>U0003 (\$100) or 87502 (\$95.80) Infectious agent detection by nucleic acid (DNA or RNA); influenza virus, for multiple types or sub-types, includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, first 2 types or sub-types or 87662 x 2 (\$51.31 x 2 = \$102.62) Infectious agent detection by nucleic acid (DNA or RNA); Zika virus, amplified probe technique</p>	<p>While the U0003 was administratively priced, the rate represents a close approximation of the lab resources required. If this isn't eligible for crosswalk recommend consideration of 87502 or 87662.</p> <p>87502 represents similar methodology and resources Both tests detect multiple types/sub-types of virus and both are performed by amplified probe technique.</p> <p>87662 with a multiplier of 2.0 accounts for the additional costs associated with rapid development to address the public health emergency, added supply expense, additional reporting requirements and the resources required for EUA.</p>