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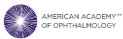
Reimbursement Considerations: Coding and Coverage

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Disclosures

- I have no relevant financial interests or relationships to disclose.

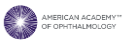


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Who Pays for Physician Services?

- Government/Public – CMS (Centers for Medicare and Medicaid Services)
 - Medicare
 - Medicaid
- Commercial
 - Medicare Advantage
 - Non-Medicare
 - ACA insurance exchanges
- Self – could be no insurance or high deductible

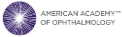


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Medicare Coverage

- According to the Social Security Act 1862(a)(1) which states
- “reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member”
- 3 pathways for research coverage
 - Coverage with Evidence Development – NCDs
 - Clinical trial policy
 - Cover routine costs but not the intervention
 - IDE study
 - Routine costs but not the intervention

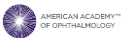


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Medicaid

- Physician payment levels are determined at the individual state level.
- Actual dollar amounts vary widely when examined as a percentage of Medicare. Usually less.
- Not all fees are RVUs based.
- Not usually increasing



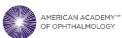
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Commercial Coverage

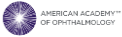
- Each with own literature review and coverage pathways
- Annual reviews/updates are possible
- Don't usually cover investigational work or new services (eg, Cat III)



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How Are CPT Codes Created?

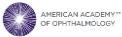


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Category I CPT Codes

- Requirements: devices and drugs must be FDA-approved
 - Performed by many US physicians or qualified health professionals
 - Frequency consistent with intended clinical use
 - Consistent with current medical practice
 - Clinical efficacy documented with peer-reviewed publications on US populations
- Coverage and payment: usually covered by CMS in Part B
 - RUC recommends value to CMS for approval
 - Commercial carriers typically follow, but often with a delay
 - Device payments typically bundled into facility reimbursement based on APC
- New codes trigger re-valuation of existing codes in the same "family"



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Category III CPT Codes

- Emerging technology
- Requirements: performed in humans, plus
 - Support by ≥1 CPT or HCPAC Advisor, OR
 - Clinical efficacy supported by peer-reviewed literature (in English), OR
 - IRB approval, ongoing US trial, or evidence of evolving clinical utilization
- Codes expire after 5 years, may be renewed or apply for Category I
- Coverage and payment: determined individually by regional MACs
 - Commercial carriers often deny as investigational
 - No prescribed rules for coverage or for physician payment
 - Facility payment per APC in Medicare



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How Are Procedures Valued?



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Payment Based On Relative Value

- Resource-Based Relative Value Scale (RBRVS)
 - Prior to the RBRVS, Medicare paid on a usual, customary and reasonable (UCR) basis
 - William Hsiao of Harvard published the RBRVS in JAMA in 1988
 - Medicare payment policy switched to the RBRVS in 1992 by statute
- Payment is based on Relative Value Units (RVUs)
 - Physician work: WRVUs
 - Practice expense: PERVUs
 - Professional liability insurance cost: PLIRVUs
 - TOTAL VALUE = (WRVU + PERVU + PLIRVU) x Conversion factor (2019 = \$36.04)

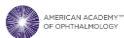


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Who Determines RVUs?

- "The RUC" = AMA/Specialty Society RVS Update Committee
 - A committee primarily composed of representatives from ABMS specialties
 - 28 voting positions
 - 2/3 supermajority needed to recommend a value
 - RVU recommendations passed on to CMS as advice
- CMS
 - Makes final value determinations
 - Published in proposed and final rules for Medicare Physician Fee Schedule
 - Acceptance rate varies but is often around 90%
- Medicare "does not pay cost".



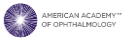
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Concept of Relativity

- Work values should be in line with other codes reviewed by the RUC
 - Different values for similar-timed codes only if there is a difference of intensity of physician work per unit time (IWPUT) – not likely in imaging

2019 Values	92227 Remote Retinal Imaging	92250 Fundus Photography	92134 OCT post seg	93000 EKG Complete	71047 Chest X-ray 3 views
IST (min)	0	10	10	5	4
PO waits	0	0	0	0	0
Total physician time	0	12	11	7	6
Fee	\$14	\$52	\$42	\$17	\$40

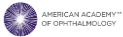


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Practice Expense RVUs

- Based on
 - Clinical staff time
 - Equipment costs and time used
 - Non-disposable instruments, capital equipment – amortized over 5 or more years
 - Package for standard exam lane equipment
 - Supplies, including package for exam supplies
- Determination is more formulaic than physician work values
 - CMS takes costs and then amortizes over a certain time period
- A significant component of total RVUs with imaging services
 - $92134 = 0.45 (\text{work}) + 0.69 (\text{PE}) + 0.02 (\text{PLI})$

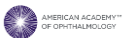


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Professional Liability Expense RVUs

- Less than 5% of total \$ value
- Based on national medical liability premiums
- Specialty-specific
 - Scale runs from 1.00 (chiropractic, optometry) to 13.02 (neurology)
 - Ophthalmology: 2.16



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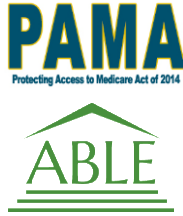
Why Are Codes Revalued?



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The Congressional Mandate

- Protecting Access to Medicare Act of 2014
 - Law to re-allocate ~1 billion dollars per year through 2020 by reducing “mis-valued codes” (PLAW pg 35)
- Achieving a Better Life Experience (ABLE) Act of 2014
 - Accelerated implementation of PAMA



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Who Brings Codes up for Review?

- RUC
- CMS
- Public

130 STAT. 1072 PUBLIC LAW 113-10—APR. 4, 2014

AN ACT TO PROTECT ACCESS TO MEDICARE BY RESTRICTING THE ABILITY OF THE MEDICARE PAYOR TO REVOKE COVERAGE FOR SERVICES PROVIDED BY HEALTH CARE PROFESSIONALS WHO ARE LICENSED IN THE STATE IN WHICH THE SERVICES ARE PROVIDED, TO AMEND THE MEDICARE ACT, TO ACCELERATE IMPLEMENTATION OF THE PROTECTING ACCESS TO MEDICARE ACT OF 2014, TO AMEND THE MEDICARE ACT TO REDUCE THE FEDERAL DEFICIT AND TO ENACT OTHER AMENDMENTS TO THE MEDICARE ACT, TO AMEND THE MEDICARE ACT TO REDUCE THE FEDERAL DEFICIT AND TO ENACT OTHER AMENDMENTS TO THE MEDICARE ACT, AND TO AMEND THE MEDICARE ACT TO REDUCE THE FEDERAL DEFICIT AND TO ENACT OTHER AMENDMENTS TO THE MEDICARE ACT.

SEC. 101. (a) The Secretary shall—

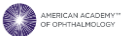
1. establish a process for the identification and review of services that are provided by health care professionals who are licensed in the State in which the services are provided;
2. conduct such research and analysis as may be necessary to identify such services;
3. conduct such research and analysis as may be necessary to determine whether such services are reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the diagnosis or treatment of an illness or injury or to prevent an illness or injury;
4. conduct such research and analysis as may be necessary to determine whether such services are reasonable and necessary for the diagnosis or treatment of an illness or injury or to prevent an illness or injury, taking into account the special considerations relating to such services;
5. conduct such research and analysis as may be necessary to determine whether such services are reasonable and necessary for the diagnosis or treatment of an illness or injury or to prevent an illness or injury, taking into account the special considerations relating to such services;
6. conduct such research and analysis as may be necessary to determine whether such services are reasonable and necessary for the diagnosis or treatment of an illness or injury or to prevent an illness or injury, taking into account the special considerations relating to such services;
7. conduct such research and analysis as may be necessary to determine whether such services are reasonable and necessary for the diagnosis or treatment of an illness or injury or to prevent an illness or injury, taking into account the special considerations relating to such services;
8. conduct such research and analysis as may be necessary to determine whether such services are reasonable and necessary for the diagnosis or treatment of an illness or injury or to prevent an illness or injury, taking into account the special considerations relating to such services;

(b) The Secretary shall report to the Committee on the Results and Findings of the Secretary's Review of the Medicare Program, as defined in section 1395gg(a)(1), not later than 180 days after the date of enactment of this Act, and annually thereafter, the results of the review conducted under this section, including a list of the services that are provided by health care professionals who are licensed in the State in which the services are provided, and the Secretary's determination of whether such services are reasonable and necessary for the diagnosis or treatment of an illness or injury or to prevent an illness or injury, taking into account the special considerations relating to such services.

(c) The Secretary shall report to the Committee on the Results and Findings of the Secretary's Review of the Medicare Program, as defined in section 1395gg(a)(1), not later than 180 days after the date of enactment of this Act, and annually thereafter, the results of the review conducted under this section, including a list of the services that are provided by health care professionals who are licensed in the State in which the services are provided, and the Secretary's determination of whether such services are reasonable and necessary for the diagnosis or treatment of an illness or injury or to prevent an illness or injury, taking into account the special considerations relating to such services.

(d) The Secretary shall report to the Committee on the Results and Findings of the Secretary's Review of the Medicare Program, as defined in section 1395gg(a)(1), not later than 180 days after the date of enactment of this Act, and annually thereafter, the results of the review conducted under this section, including a list of the services that are provided by health care professionals who are licensed in the State in which the services are provided, and the Secretary's determination of whether such services are reasonable and necessary for the diagnosis or treatment of an illness or injury or to prevent an illness or injury, taking into account the special considerations relating to such services.

(e) The Secretary shall report to the Committee on the Results and Findings of the Secretary's Review of the Medicare Program, as defined in section 1395gg(a)(1), not later than 180 days after the date of enactment of this Act, and annually thereafter, the results of the review conducted under this section, including a list of the services that are provided by health care professionals who are licensed in the State in which the services are provided, and the Secretary's determination of whether such services are reasonable and necessary for the diagnosis or treatment of an illness or injury or to prevent an illness or injury, taking into account the special considerations relating to such services.

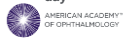


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Types of CMS Screen

- Anything they want to bring up plus:
 - Rapid growth in volume
 - Substantial change in practice expense
 - Valuation anomalies within a family
 - Rank order anomalies
 - Exceptionally high value codes
 - High cost supplies
 - Change in typical site of service
 - Codes billed together on the same day
- High IWPUT
- Harvard-valued codes with annual utilization >30,000
- HHS Secretary requests for review
 - Often initiated by local carrier medical director, who may believe a code is overvalued

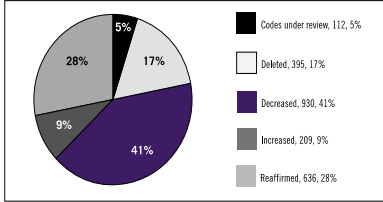


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The Result

- 2,300 codes reviewed
- \$4.5 billion redistributed

RUC Potentially Misvalued Services Project by Total Number of Misvalues in Project (2,282)



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Coverage Policies - Commercial

- Typically the fee schedule is similar to Medicare, but with a different conversion factor
- Formal process – often annual
- Responses required on relatively short turn around
- With consolidation in the industry these are becoming more rigorous

Anthem Medical Policy

Subject: Investigative melanocytic (Lutera™)
Effective Date: 03/01/18
Status: New
Publication Date: 12/22/18
Last Review Date: 03/01/18

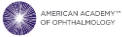
Policy Statement:
 This document addresses the use of investigative melanocytic (Lutera™, Squibb Therapeutics, Philadelphia, PA), a gene sequencing therapy intended to treat retinal dystrophies caused by mutations in the RP68 gene mutation.
 Please refer to the following table describing reporting codes being to investigate and related diseases, including the related level of evidence.
 * ICD-10-CM Coding: Health of an Individual's Capacity for Selected Diseases

Position Statement:
Medically Necessary:
 The use of investigative melanocytic gene therapy is considered medically necessary in individuals who meet all of the following criteria:
 1. A diagnosis of retinal dystrophy (as confirmed by OCT) in both eyes, and
 2. At least 1 year of age, and
 3. Carriers of the RP68 gene mutation, sufficient viable retinal cells as determined by non-invasive means, such as optical coherence tomography (OCT) and/or fundus photography, as evidenced by use of the following:
 1. Areas of retina within the posterior pole of greater than 100 µm thickness shown on OCT, or
 2. Thick or thin disc areas of more than 200 µm or 100 µm respectively, respectively, within the posterior pole, or
 3. Remaining visual field within 30 degrees of fixation as measured by a Gold perimeter or equivalent.
 4. For each eye indicated for treatment, have not had intravitreal surgery within 6 months.
 Note: Investigative melanocytic gene therapy will be covered retroactively within a program number or retroactively pending to use retroactively for four months after treatment.



Coverage Medicare

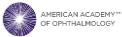
- Part A – Hospitalization
 - Medicare payroll tax
- Part B – physician and outpatient services
 - Premiums from beneficiaries plus taxpayers
- Part D – outpatient drugs (not including physician administered)
- Part C – commercial plan including Parts B and D
 - Must offer same coverages as in Part B



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Coverage Medicare

- Administered by contracted companies – Medicare Administrative Carriers

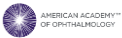


Coverage Policies - Medicare

- National Coverage Determinations (NCD) – CMS Policy

National Coverage Determination (NCD) for Ocular PHOTODYNAMIC Therapy (OPT)
(10.2.1)

Tracking Information		
Publication Number	Manual Section Number	Manual Section Title
100.8	802.7	Covered PHOTODYNAMIC Therapy (OPT)
Revision Number	Effective Date of this Version	Implementation Date
3	8/20/01	7/16/01
Description Information		
Benefit Category Physician's Services		
<small>Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.</small>		
Benefit Service Description 1. General Covered: Photodynamic Therapy (PDT) is used in the treatment of ophthalmologic diseases, specifically for age-related macular degeneration (AMD), in a clinical eye disease setting. The use of OPT during the course of an ophthalmologic procedure to treat retinal neovascularization is covered when used by a physician or ophthalmologist. Effective July 1, 2001, OPT with verteporfin was approved for a diagnosis of neovascular AMD with predominantly classic and occult choroidal neovascularization (CNV) lesions from the onset of classic CNV (usually 6-90 days prior to the start of the therapy) and for the treatment of AMD in the absence of a neovascular diagnosis. On September 27, 2006, the Centers for Medicare & Medicaid Services (CMS) announced its intent to cover OPT with verteporfin for AMD patients with occult		



Coverage Policies - Medicare

- Local Coverage Determinations (LCD) – Contractor Policy
 - Increasingly coordinated
 - Annual review process
 - Local review committee of Carrier Advisors – this is changing to a more contractor-wide process

LCD Information

Document Information	
LCD ID L30038	Original Effective Date For services performed on or after 10/01/2015
LCD Title Scanning Computerized Ophthalmic Diagnostic Imaging	Revision Effective Date For services performed on or after 01/01/2018
Proposed LCD in Comment Period No	Revision Ending Date No
Source Proposed LCD CL30038	Retirement Date N/A
AMA CPT / ADA CPT / AHA NCSG Copyright Statement CPT codes, descriptions and other data are copyright 2018 American Medical Association. All Rights Reserved. Applicable FARS/DFARS apply.	Notice Period Start Date 12/07/2017
Current Denial Terminology © 2018 American Dental Association. All rights reserved.	Notice Period End Date 01/01/2018



Novitas – Find these on www.cms.gov

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	APPLICABLE	STATE
Novitas Solutions, LLC	A and B-IMC	0411-IMC-A	J-19	Colorado
Novitas Solutions, LLC	A and B-IMC	0411-IMC-A	J-19	Connecticut
Novitas Solutions, LLC	A and B-IMC	0411-IMC-A	J-19	Delaware
Novitas Solutions, LLC	A and B-IMC	0411-IMC-A	J-19	District of Columbia
Novitas Solutions, LLC	A and B-IMC	0411-IMC-A	J-19	Florida
Novitas Solutions, LLC	A and B-IMC	0411-IMC-A	J-19	Georgia
Novitas Solutions, LLC	A and B-IMC	0411-IMC-A	J-19	Idaho
Novitas Solutions, LLC	A and B-IMC	0411-IMC-A	J-19	Illinois
Novitas Solutions, LLC	A and B-IMC	0411-IMC-A	J-19	Indiana
Novitas Solutions, LLC	A and B-IMC	0411-IMC-A	J-19	Iowa
Novitas Solutions, LLC	A and B-IMC	0411-IMC-A	J-19	Kansas
Novitas Solutions, LLC	A and B-IMC	0411-IMC-A	J-19	Kentucky
Novitas Solutions, LLC	A and B-IMC	0411-IMC-A	J-19	Louisiana
Novitas Solutions, LLC	A and B-IMC	0411-IMC-A	J-19	Maine
Novitas Solutions, LLC	A and B-IMC	0411-IMC-A	J-19	Massachusetts
Novitas Solutions, LLC	A and B-IMC	0411-IMC-A	J-19	Michigan
Novitas Solutions, LLC	A and B-IMC	0411-IMC-A	J-19	Minnesota
Novitas Solutions, LLC	A and B-IMC	0411-IMC-A	J-19	Mississippi
Novitas Solutions, LLC	A and B-IMC	0411-IMC-A	J-19	Missouri
Novitas Solutions, LLC	A and B-IMC	0411-IMC-A	J-19	Montana
Novitas Solutions, LLC	A and B-IMC	0411-IMC-A	J-19	Nebraska
Novitas Solutions, LLC	A and B-IMC	0411-IMC-A	J-19	Nevada
Novitas Solutions, LLC	A and B-IMC	0411-IMC-A	J-19	New Hampshire
Novitas Solutions, LLC	A and B-IMC	0411-IMC-A	J-19	New Jersey
Novitas Solutions, LLC	A and B-IMC	0411-IMC-A	J-19	New Mexico
Novitas Solutions, LLC	A and B-IMC	0411-IMC-A	J-19	New York
Novitas Solutions, LLC	A and B-IMC	0411-IMC-A	J-19	North Carolina
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Novitas Solutions, LLC	A and B-IMC	0411-IMC-A	J-19	Oklahoma
Novitas Solutions, LLC	A and B-IMC	0411-IMC-A	J-19	Oregon
Novitas Solutions, LLC	A and B-IMC	0411-IMC-A	J-19	Pennsylvania
Novitas Solutions, LLC	A and B-IMC	0411-IMC-A	J-19	Rhode Island
Novitas Solutions, LLC	A and B-IMC	0411-IMC-A	J-19	South Carolina
Novitas Solutions, LLC	A and B-IMC	0411-IMC-A	J-19	South Dakota
Novitas Solutions, LLC	A and B-IMC	0411-IMC-A	J-19	Tennessee
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Novitas Solutions, LLC	A and B-IMC	0411-IMC-A	J-19	Utah
Novitas Solutions, LLC	A and B-IMC	0411-IMC-A	J-19	Vermont
Novitas Solutions, LLC	A and B-IMC	0411-IMC-A	J-19	Virginia
Novitas Solutions, LLC	A and B-IMC	0411-IMC-A	J-19	Washington
Novitas Solutions, LLC	A and B-IMC	0411-IMC-A	J-19	West Virginia
Novitas Solutions, LLC	A and B-IMC	0411-IMC-A	J-19	Wisconsin
Novitas Solutions, LLC	A and B-IMC	0411-IMC-A	J-19	Wyoming



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