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CMS Proposed Rule for Ophthalmic Office Based Surgery

February 9, 2022

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1751-F
Mail Stop C4-01-26
7500 Security Blvd
Baltimore, MD 21244
Via email to DivisionofPractitionerServices@cms.hhs.gov

Re: Medicare Program: CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies
Attention: Division of Practitioner Services, Potentially Misvalued Codes

Dear Administrator Brooks-LaSure:

I am writing to you today on behalf of iOR Partners, a company dedicated to the provision of high quality, cost efficient, ophthalmic office-based surgery. Over the past decade, we have assisted over 80 ophthalmologists to safely provide ophthalmologic surgical services in an office-based setting.

Background

In 2015, the Centers for Medicare & Medicaid Services (CMS) generated a Request for Information from the Ophthalmology community to investigate Office-based or "non-facility" cataract surgery for the 2016 Medicare Physician Fee Schedule (MPFS) Proposed Rule. In the Final Rule for 2016, CMS acknowledged a future need for these services.

> *"Advancements in technology have significantly reduced operating time and improved both the safety of the procedure and patient outcomes. As discussed in the proposed rule, we believe that it now may be possible for cataract surgery to be furnished in an in-office surgical suite, especially for routine cases. Cataract surgery patients require a sterile surgical suite with certain equipment and supplies that we believe could be a part of a non-facility based setting that is properly constructed and maintained for appropriate infection prevention and control."*

Since that time, in the United States over 33,000 patients have safely received cataract surgery in an Office-Based Surgery (OBS) setting. This is consistent with the American Academy of Ophthalmology's statement that they would support the option of office-based cataract surgery with adequate safety standards.[1]

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The COVID-19 pandemic had a significant role in the migration of surgical services from the facility to the office-based setting, which has continued beyond the height of infection in the US. It is projected that the backlog of cataract surgeries will be between 1.1 and 1.6 million Medicare cases two years after pandemic shutdowns start to ease.[2] COVID-19 also is causing delays in care and claims processing within the VA system. It is estimated that with additional eligibility for Agent Orange claims, in addition to the William M Thornberry National Defense Authorization Act, that the backlog within the VA System is now double its pre-COVID rate.[2]

Compounding this issue is the fact that there are 27 States with high Certificate of Need regulatory hurdles that create barriers to entry for Ambulatory Surgery Center construction. The market demand for office-based surgical care has caused ophthalmologic surgeons to evaluate alternatives to better serve beneficiaries. These advances have demonstrated that safe and effective cataract surgery, Micro-Invasive Glaucoma Surgery (MIGS), and multiple retinal procedures can safely be performed in the non-facility office setting.

Furthermore, the demand for ophthalmic surgery continues to grow with the aging Baby Boomer population. In 2017 the U.S. population of those age 65 and older was 51 million, over half of whom – 25.7 million – had cataracts. Cataract surgery was the most common outpatient surgery, with 3.8 million surgeries performed.[3] By 2032 it is projected that the number of individuals in the U.S. with cataracts will increase to 38.5 million and by 2050 that number will reach 45.6 million.

Discussion

With the continued advances in surgical technology, strong evidence of patient safety, greater patient access to affordable care, as well as quantifiable cost savings for the Medicare system, we believe that it is appropriate for CMS to value the following procedures in the Office (Site of Service 11) setting in the CY 2023 Medicare Physician Fee Schedule.

Cataract Surgery:

- **66984** - Extracapsular cataract removal with insertion of intraocular lens prosthesis (one stage procedure), manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification)
- **66982** - Extracapsular cataract removal with insertion of intraocular lens prosthesis (one stage procedure), manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification
- **66991** - Extracapsular cataract removal w/IOL insertion; with insertion of intraocular (e.g., trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more
- **66989** - Extracapsular cataract removal w/IOL insertion, complex; with insertion of intraocular (e.g., trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more
- **65820** - Goniotomy
- **66174 -** Transluminal dilation of aqueous outflow canal; without retention of device or stent.

Retinal Procedures

- **67015** –Aspiration or release of vitreous, subretinal or choroidal fluid, pars plana approach (posterior sclerotomy)

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- **67036** – Vitrectomy, mechanical, pars plana approach
- **67039** – Vitrectomy, mechanical, pars plana approach; with focal endolaser photocoagulation
- **67040** – Vitrectomy, mechanical, pars plana approach; with endolaser panretinal photocoagulation
- **67041** – Vitrectomy, mechanical, pars plana approach; with removal of preretinal cellular membrane (eg, macular pucker)
- **67042** – Vitrectomy, mechanical, pars plana approach; with removal of internal limiting membrane of retina (eg, for repair of macular hole, diabetic macular edema), includes, if performed, intraocular tamponade (ie, air, gas or silicone oil)
- **67043** – Vitrectomy, mechanical, pars plana approach; with removal of subretinal membrane (eg, choroidal neovascularization), includes, if performed, intraocular tamponade (ie, air, gas or silicone oil) and laser photocoagulation
- **67108** – Repair of retinal detachment; with vitrectomy, any method, including, when performed, air or gas tamponade, focal endolaser photocoagulation, cryotherapy, drainage of subretinal fluid, scleral buckling, and/or removal of lens by same technique
- **67113** - Repair of complex retinal detachment (eg, proliferative vitreoretinopathy, stage C-1 or greater, diabetic traction retinal detachment, retinopathy of prematurity, retinal tear of greater than 90 degrees), with vitrectomy and membrane peeling, including, when performed, air, gas, or silicone oil tamponade, cryotherapy, endolaser photocoagulation, drainage of subretinal fluid, scleral buckling, and/or removal of lens

Surgical Safety Data

In reviewing the feedback from the 2016 comment period, the primary concern was around safety. We agree that patient safety is of primary importance. Six years later there is a preponderance of data which supports that safe and effective surgical intervention for several ophthalmologic surgeries can be safely performed in the office-based surgery setting.

Office-based surgery has been proven to be safe with effective outcomes that are comparable or superior to cataract surgeries performed in an ASC. The largest U.S. retrospective study of 21,501 cataract surgeries (13,507 patients) conducted at Kaiser Permanente Colorado found that office-based surgery efficacy outcomes were consistently excellent, with a safety profile expected of minimally invasive cataract procedures performed in an ASC or HOPD. This study concluded "Office-based efficacy outcomes were consistently excellent, with a safety profile expected of minimally invasive cataract procedures performed in ASCs and HOPDs."[4]

There have been over 12,000 ophthalmologic procedures tracked by iOR Partners, a management entity that collaborates with ophthalmic surgeons in developing licensed and accredited surgical suites in a physician's office. These suites operate at the same safety standards of care as an ASC or HOPD environment.

iOR Office-Based Surgery Safety Profile

- Endophthalmitis – 0.03%
- Unplanned Vitrectomy – 0.13%
- Referred to Retina – 0.057%

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- Return to the OR – 0.066% (most for removal of residual cortex)
- TASS or significant iritis – 0.033% (single outbreak at 1 center)
- Corneal Edema – 0.024%
- Referred to Hospital – 0.0082% (nausea and unable to keep food and fluids down)

These results, as do the Kaiser data, demonstrate outcomes comparatively similar to ASC procedures. Importantly, these data also demonstrate no life or vision threatening intraoperative or postoperative incidents. Combined this data set represents over 33,000 ophthalmic procedures that were safely performed in the office setting.

Representative Practice Expense

Using code 66984 as an example, iOR Partners has estimated the practice expense for the procedure when performed in the office setting.

Staffing:

Labor Code	Description	Number of staff	Minutes	
L038A	COMT/COT/RN/CST	2	45	
L051A	RN	2	45	

Equipment:

Equip_Category	Equip_Code	Description	LIFE	PRICE	Units
DOCUMENTATION	ED043	refrigerator, vaccine, temperature monitor w-alarm, security mounting w-sensors, NIST certificates	10	$1,000.00	1
FURNITURE	EF009	chair, medical recliner	10	$1,542.81	1
FURNITURE	EF011	crash cart (unstocked)	10	$1,839.34	2
FURNITURE	EF015	mayo stand	15	$526.78	1
FURNITURE	EF027	table, instrument, mobile	15	$582.96	2
FURNITURE	EF031	table, power	10	$6,030.20	1
LABORATORY	EP021	incubator	10	$1,201.35	1
OTHER EQUIPMENT	EQ004	CO2 respiratory profile monitor	7	$6,039.20	1
OTHER EQUIPMENT	EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	7	$3,730.75	2
OTHER EQUIPMENT	EQ097	defibrillator	5	$2,394.30	1
OTHER EQUIPMENT	EQ138	instrument pack, medium ($1500 and up)	4	$1,500.00	7
OTHER EQUIPMENT	EQ183	microscope, operating	5	$7,047.50	1
OTHER EQUIPMENT	EQ235	suction machine (Gomco)	10	$767.48	1
		Phaco with handpieces	3	$76,207.32	1
		camera system for microscope	5	$8,998.00	1
		Sterilizer	3	$4,499.00	1
		Surgeon's Stool	5	$2,895.00	1
		UPS Battery Backup	1	$219.00	1
		wheelchair	7	$109.51	1

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Supplies:

CATEGORY	Supply_Code	DESCRIPTION	Price x Units
Pharmacy, Rx	SH056	phenylephrine 2.5% ophth (Mydfrin)	2.082
Pharmacy, Rx	SH058	proparacaine 0.5% ophth (Ophthaine, Alcaine)	1.194
Pharmacy, Rx	SH073	tropicamide 1% ophth (Mydriacyl)	0.743
Pharmacy, Rx	SH074	water, sterile for irrigation (250-1000ml uou)	2.47
Pharmacy, Rx	SH078	balanced salt soln (BSS) (15ml uou)	1.815
Pharmacy, NonRx	SJ053	swab-pad, alcohol	0.265
Office Supply, Grocery	SK075	skin marking pen, sterile (Skin Skribe)	1.334
Office Supply, Grocery	SK087	water, distilled	0.0165
Office Supply, Grocery	SK114	tissue (Kleenex)	1.695
Lab	SL038	cup-container, sterile, graduated 1000ml	1.145
Lab	SL088	lint-free cloth	0.2215
Lab	SL157	cup, sterile, 8 oz	0.561
Infection Control	SM002	autoclave bag	0.35
Infection Control	SM003	autoclave tape	0.355
Infection Control	SM011	cleaning brush, instruments	3.775
Infection Control	SM022	sanitizing cloth-wipe (surface, instruments, ec	0.58
Infection Control	SM023	scrub brush (impregnated)	6.889
Infection Control	SM024	soap, liquid, antibacterial	0.373
		IOL	150
		Lidocaine HCL, PF 1% 2ml	5.83
		Epinephrine PF 1mg/ml 1ml	13.88
		Provisc 0.85ml 27g oph viscosurgical dev	70.3
		balanced salt soln (BSS) (500ml)	5.51
		phaco pack	157.79
		PredMoxi suspension 5ml	35.2
		disposable slit kife	8.33
		disposable straight knife	4.5
Occational Use items			
Hypodermic, IV	SC104	suture, nylon, 10-0	2.302
		Vitrectomy Pack	37.8
		VisionBlue 0.06% ophthalmic solution	12.68
		disposable iris retractor	11.6
		Miostat 0.01% 1.5ml	9.442
		Malyugin ring	26.634
		Capsule Retractors	23.334

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Conclusion

Providing reimbursement for these procedures in the non-facility setting would be consistent with a 2019 Executive Order titled, "Executive Order on Protecting and Improving Medicare for Our Nation's Seniors." The EO states in Section 7 Rewarding Care Through Site Neutrality specifically that "The Secretary [of HHS] shall ensure that Medicare payments and policies encourage competition and a diversity of sites for patients to access care."[5] Office-based surgery and CMS recognition of payment in Site of Service Differential in Site of Care 11 directly align with this directive.

Thank you for considering our request. Should you have questions, please contact me at jwachtman@iorpartners.com or 816-897-7670.

Sincerely,

Jim Wachtman
Chief Executive Officer
iOR Partners

[1] "Updated Cataract PPP Raises Questions About Same-Day Bilateral Cataract Surgery and Office-based Cataract Surgery." American Academy of Ophthalmology, 14 Nov. 2021. Press release.

[2] "Understanding VA's current claims backlog environment, future growth." *VAntage Point*, 27 Aug. 2021, https://blogs.va.gov/VAntage/93906/understanding-vas-current-claims-backlog-environment-future-growth/

[3] "Over 3.8 Million Cataract Surgeries Performed Every Year Data Research." iData Research, 6, Apr. 2018. https://idataresearch.com/over-3-8-million-cataract-surgeries-performed-every-year/.

[4] Ianchulev T, Litoff D, Ellinger D, Stiverson K, Packer M. Office-Based Cataract Surgery: Population Health Outcomes Study of More than 21 000 Cases in the United States. Ophthalmology. 2016 Apr;123(4): 723-8.

[5] "Protecting and Improving Medicare for Our Nation's Seniors." A Presidential Document by the Executive Office of the President, 3 Oct. 2019.