Anne Langley, JD, MPH Senior Director, Health Planning and Community Engagement Health Care Transformation and Strategic Planning 3910 Keswick Road, Suite N-2200 Baltimore MD 21211 443-997-0727 Telephone 443-997-0731 Fax alangle2@jhmi.edu



Eric Baker Program Manager, Certificate of Need Maryland Health Care Commission 4160 Patterson Avenue Baltimore, Maryland 21215 May 20, 2019

RE: White Marsh Surgery Center Certificate of Need Application Response to Completeness Questions, Docket No. 19-03-2437

Dear Mr. Baker:

Please see enclosed response to completeness question received by the Johns Hopkins Surgery Center Series ("JHSCS") on Wednesday, May 8, 2019 for the above-referenced matter.

I certify that a copy of this filing will be sent to the Baltimore County Health Officer.

Thank you for your consideration of this matter. Please contact me or Spencer Wildonger if you have any questions or need additional information.

Sincerely,

Anne Langley

#### **PART II - Project Budget**

1. Total Sources of Funds (Exh. 6, Table E) is blank in the application. Please correct the table and resubmit.

#### Applicant Response:

Please see **Exhibit CQ1.1** for a revised version of Table E, with Total Sources of Funds included.

#### PART IV - Consistency with General Review Criteria at COMAR 10.24.0l.08G(3)

#### **Charity Care Policy**

2. Your response to (a)(i) regarding the charity care policy determination references the policy. The policy states on page 2 that standardized applications for Financial Assistance and Medical Financial Hardship have been developed. Copies are attached to this policy as Exhibits A and B. No attachments were included with the policy. Please provide copies of the application forms.

#### Applicant Response:

Please see **Exhibit CQ1.2**, which includes a copy of the Financial Assistance application and the Medical Financial Hardship application.

3. Your response to (a)(ii) does not include a copy of the notice provided to patients regarding the availability of charity care. Please provide a copy of the notice that is posted and handed out to patients.

#### Applicant Response:

Please see **Exhibit CQ1.3** for a copy of the individual notice of the availability of financial assistant provided to the patients and posted in the waiting rooms.

#### Need

4. On page 40 it is stated that "There is increasing pressure from payors to perform outpatient cases in a lower cost setting when medically appropriate." Do you have documentation supporting this statement?

#### Applicant Response:

Please see **Exhibit CQ1.4** for documentation of payor pressure to shift cases to an outpatient setting when medically appropriate. Included are two notifications from Amerigroup with associated CPT codes that will no longer be reimbursed in a hospital setting as well as site of service guidelines from United Healthcare regarding surgical procedures that will only be reimbursed in an ASC.

Over the recent months, private insurers have provided the Johns Hopkins HealthCare Office of Managed Care with updates and notices that indicate which surgical procedures will no longer be reimbursed in a hospital setting. These procedures, identified by CPT code, need to be performed in an Ambulatory Surgery Center (ASC) or a provider office in order to be covered. Only services that cannot be provided safely at an ASC or office will be approved to be performed in a hospital setting, and this is determined on a case-by-case basis.

The procedures affected by these restrictions vary but include specialties such as Ear, Nose, and Throat (ENT), Urology, Gynecology, and other clinical service lines reflective of those seeking to move cases to the White Marsh Surgery Center.

#### **Design Requirement**

5. The standard call for an ASC to be compliant with FGI standard 3.7. The architect's attestation (exh. 16) refers to standard 2.7 in error. Please submit a corrected attestation from the architect.

#### Applicant Response:

The standard states that the floor plans "must be consistent with the current Facility Guidelines Institute's Guidelines for Design and Construction of Health Care Facilities (FGI Guidelines)." At the time of the effective date of the General Surgical Services chapter, Standard 3.7 was the current standard, which referred to the 2014 FGI Guidelines. However, Standard 2.7 is now the current standard, as a result of the 2014 Guidelines being updated in 2018. Therefore, the attestation from the architect is correct, in that it confirms the consistency of the floor plan with the current, 2018 FGI Guidelines.

The link below directs to the official website of the 2014 Facility Guidelines Institute:

https://www.fgiguidelines.org/guidelines/2014-fgi-guidelines/

Available on this page is a link to the Table of Contents for the 2014 FGI Guidelines for Design and Construction of Hospitals and Outpatient Facilities. This document is also attached as **Exhibit CQ1.5A**.

https://www.fgiguidelines.org/wp-content/uploads/2015/07/FGI Guidelines 2014 HOP TOC.pdf

On page 6 of the Table of Contents, it notes that section 3.7 refers to Specific Requirements for Outpatient Surgical Facilities:

## 3.7 Specific Requirements for Outpatient Surgical Facilities 311

FGI standard 3.7 is referenced in the State Health Plan For Facilities and Services: General Surgical Services chapter COMAR 10.24.11, with an effective date of January 15, 2018.

COMAR 10.24.11.05(B) Project Review Standard, (4) Design Requirements is copied below (emphasis added):

Floor plans submitted by an applicant **must be consistent with the current**Facility Guidelines Institute's Guidelines for Design and Construction of Health
Care Facilities (FGI Guidelines):

(a) A hospital shall meet the requirements in current Section 2.2 of the FGI

Guidelines.

- (b) An ASF shall meet the requirements in current Section 3.7 of the FGI Guidelines.
- (c) Design features of a hospital or ASF that are at variance with the current FGI Guidelines shall be justified. The Commission may consider the opinion of staff at the Facility Guidelines Institute, which publishes the FGI Guidelines, to help determine whether the proposed variance is acceptable.

Section 3.7 was the current version of the 2014 FGI guidelines at the time of the effective date of the General Surgical Services. As of the date of this application, the 2018 FGI guidelines are now the current version.

The link below directs to the official website of the 2018 Facility Guidelines Institute:

https://www.fgiguidelines.org/guidelines/2018-fgi-guidelines/

Available on this page is a link to the Table of Contents for the 2018 FGI Guidelines for Design and Construction of Outpatient Facilities. This document is also attached as **Exhibit CQ1.5B** 

 $\underline{https://www.fgiguidelines.org/wp\text{-}content/uploads/2018/01/FGI\text{-}Guildelines\text{-}Outpatient-}{2018\_TOC.pdf}$ 

On page 5 of the Table of Contents, it notes that now section 2.7 refers to Specific Requirements for Outpatient Surgical Facilities:

2.7 Specific Requirements for Outpatient Surgery Facilities

155

The architect's letter attests to the consistency of the floor plans with the most recent FGI Guidelines, from 2018, Standard 2.7.

# Exhibit CQ1.1



#### **TABLE E. PROJECT BUDGET**

INSTRUCTION: Estimates for Capital Costs (1.a-e), Financing Costs and Other Cash Requirements (2.a-g), and Working Capital Startup Costs (3) must reflect current costs as of the date of application and include all costs for construction and renovation. Explain the basis for construction cost estimates, renovation cost estimates, contingencies, interest during construction period, and inflation in an attachment to the application.

NOTE: Inflation should only be included in the Inflation allowance line A.1.e. The value of donated land for the project should be included on Line A.1.d as a use of funds and on line B.8 as a source of funds

		Hospital Building	Other Structure	Total
	OF FUNDS			
1. C/	APITAL COSTS			
a.				
(1				\$
(2	, , , , ,			\$
	) Site and Infrastructure			\$
(4	, , , , , , , , , , , , , , , , , , , ,			\$
(5	, , , , , , , , , , , , , , , , , , , ,	60	¢0	\$
	SUBTOTAL Renovations	\$0	\$0	Þ
b.		1	¢450,000	<b>\$450.00</b>
(1	,		\$450,000 \$170,000	\$450,00
(2	) Architect/Engineering Fees		\$170,000	\$170,00 \$95,00
(4	,		\$5,000	\$5,00 \$5,00
(4	SUBTOTAL	\$0	\$720,000	\$720,00
C.		ΨΟ	Ψ1 <b>20</b> ,000	Ψ120,00
	) Movable Equipment		\$280,000	\$280,00
,	) Contingency Allowance		\$50,000	\$50,00
	) Gross interest during construction period		ψου,σου	\$30,00
(4				<u> </u>
	SUBTOTAL	\$0	\$330,000	\$330,00
	TOTAL CURRENT CAPITAL COSTS	\$0	\$1,050,000	\$1,050,00
d.			. , ,	\$
e.				\$
	TOTAL CAPITAL COSTS	\$0	\$1,050,000	\$1,050,00
2. Fi	nancing Cost and Other Cash Requirements	***	+ 1,000,000	+ 1,000,00
a.				\$
b.				\$
С	CON Application Assistance			·
	c1. Legal Fees			\$
	c2. Other (Specify/add rows if needed)			\$
d.	Non-CON Consulting Fees			
	d1. Legal Fees			\$
	d2. Other (Specify/add rows if needed)			\$
e.	Debt Service Reserve Fund			\$
f	Other (Specify/add rows if needed)			\$
	SUBTOTAL	\$0	\$0	\$
3. W	orking Capital Startup Costs			\$
	TOTAL USES OF FUNDS	\$0	\$1,050,000	\$1,050,00
	es of Funds			
1. Ca			\$1,050,000	\$1,050,00
	hilanthropy (to date and expected)			\$
	uthorized Bonds			\$
	terest Income from bond proceeds listed in #3			\$
	ortgage			\$
	orking Capital Loans			\$
	rants or Appropriations	1		Φ.
a.				\$ \$
<u>b.</u>		+		<u> </u>
8. Of	Local ther (Specify/add rows if needed)	+		<u> </u>
0. U	TOTAL SOURCES OF FUNDS	\$0	\$1,050,000	\$1,050,00
	TOTAL SOUNCES OF FUNDS	·	Other Structure	Total
nnual I a	ase Costs (if applicable)	Hospital Building	other structure	i Ulai
	and			\$
	uilding		\$34,340	 \$34,34
	ajor Movable Equipment		<b>₽</b> 34,340	\$34,34 \$
J. 191				
	inor Movable Equipment			\$

<sup>\*</sup> Describe the terms of the lease(s) below, including information on the fair market value of the item(s), and the number of years, annual cost, and the interest rate for the lease.

# Exhibit CQ1.2



## **FINANCIAL ASSISTANCE APPLICATION**

Patient Name:	
Patient Address:	
(Include Zip Code)	
Medical Record #:	
Date:	
Family size:	
Family Income for twelve (12) calendar months p (Attach supporting documentation)	preceding date of this application:
Below 200% Federal Poverty Level (Yes/No):	
All documentation submitted becomes part of thi	s application. Supporting Documentation may include:
<ul><li>Pay stubs</li><li>W-2s</li><li>1099s</li><li>Workers' compensation</li></ul>	<ul> <li>Social Security or disability award letters</li> <li>Tax returns</li> <li>Explanation of Benefits to support Medical Debt</li> </ul>
All the information submitted in the application is information and belief.	true and accurate to the best of my knowledge,
	Date:
Applicant's signature	
	<del>_</del>
Relationship to Patient	
For Internal Use: Reviewed By:	
	Date:

### **MEDICAL FINANCIAL HARDSHIP APPLICATION**

Surgery Center:	
Patient Name:	
Patient Address:(Include Zip Code)	
Medical Record #:	
Date:	
Family size:	
Family Income for twelve (12) calendar months (Attach supporting documentation)	preceding date of this application:
Below 200% Federal Poverty Level (Yes/No):_	
All documentation submitted becomes part of the	nis application.
Applicant's signature  Relationship to Patient	Date:
For Internal Use:	
Reviewed By:	Date:
Income:	25% of income =
Medical Debt:	Percentage of Allowance:
Reduction:	Balance Due:
Monthly Payment Amount:	Length of Payment Plan: months

# Exhibit CQ1.3



## Johns Hopkins Surgery Centers White Marsh Surgery Center

4924 Campbell Boulevard Suite 250 Nottingham, MD 21236

## \*\*\*ATTENTION PATIENTS\*\*\*

If you need assistance paying for your surgical procedure, whether or not you have insurance, please see the receptionist for more information or contact our billing and financial assistance office

(443) 442-2700, option 4

# Exhibit CQ1.4



## **Exhibit CQ1.4**

- 1. Amerigroup outpatient general surgery provider update (Page 14)
- 2. Amerigroup outpatient gynecology provider update (Page 17)
- 3. United Healthcare site of service guidelines for certain outpatient surgical procedures (Page 21)

#### **Outpatient general surgery precertification initiative**

Amerigroup Community Care requires outpatient general surgery procedures to be provided at an ambulatory surgery center (ASC) or provider office unless precertified at a hospital in the following counties: Baltimore City, Baltimore County, Howard County, Montgomery County and Prince George's County. Effective March 1, 2019, only the services that cannot be provided safely and effectively at a freestanding ASC or an office will be approved to be performed at the hospital.

#### What is the impact of this change?

Unless there is a medical reason for providing the outpatient general surgery procedure listed on the provided code list in a hospital, the services must be performed at a freestanding ASC or in an office. Members who are 18 years of age or younger are excluded from this initiative.

Providers should review Section 1 of this communication for a list of procedure codes that will require precertification to be performed in a hospital. For code-specific precertification requirements, please refer to https://providers.amerigroup.com/MD > Provider Resources & Documents > Quick Tools > select Precertification Lookup Tool.

Providers should review Section 2 for a list of participating ASCs that offer general surgery services.

This initiative applies to providers in Baltimore City, Baltimore County, Howard County, Montgomery County and Prince George's County and covers all general surgery codes listed on our provider website.

#### How do I obtain precertification?

You must call Provider Services at 1-800-454-3730 and provide clinical documentation showing a medical reason why the member needs to have an outpatient general surgery procedure done in a hospital.

#### What if I need assistance?

If you have questions about this communication or need assistance with any other item, contact your local Provider Relations representative or call Provider Services at 1-800-454-3730.

Thank you for the quality care you provide to our members.

<sup>\*</sup> Participating provider listings change periodically. For the latest list of participating ASCs offering general surgery services, see our provider directory at https://providers.amerigroup.com/MD or call Provider Services at 1-800-454-3730 to find the facility most convenient for your patient.

#### Medical necessity criteria

List of relevant case or member-specific facts that support the use of hospital-based or regulated space procedures. Reasons may include but are not limited to:

- Ability of a freestanding site of service to safely and adequately accommodate and support the member in the course of treatment because of specialized equipment or staff skill set
- Access or availability of a freestanding site of service within the 30-minute or 30-mile standard
- Member is 18 years of age or younger
- Suffering from any of the following conditions:
  - Respiratory disease
    - Asthma
    - Chronic obstructive pulmonary disease/emphysema
    - Sleep apnea and actively using continuous positive airway pressure
  - Cardiac disease
    - Congestive heart failure symptomatic in the last month (any episode of documented or active congestive heart failure, emergency room visit, admission, worsening chronic congestive heart failure, recent adjustment of medicines, etc.)
    - Myocardial infarction within the last six weeks
    - Arrhythmia within the last six weeks
    - Pacemaker in place
    - Automatic implantable cardioverter defibrillator in place
    - On warfarin or another anticoagulant
    - On Plavix® or another platelet inhibitor
- Severe anemia/hematocrit <25%, platelets <30,000</li>
- Morbid obesity/body mass index >40
- History of any complication with sedation, anesthesia or surgery

#### Section 1: Procedure codes required for precertification in a hospital

The following procedure codes will require precertification to be performed in a hospital.

Procedures performed in association with an ER visit or associated with an outpatient surgery performed at a hospital on the same day will not require precertification.

11042	11043	15823	15830	15832	17107	17110	17111	31231	31235
31237	31238	31254	31255	31256	31267	31575	31579	36430	36512
36514	47562	47563	49060	49083	49084	49320	49321	49322	49324
49329	49520	49521	49525	49550	49587	49650	49651	49652	49653
49654	49655	49656	64400	64402	64405	64417	64425	64430	64435
64447	64450	64479	64483	64484	64708	64713	64718	64721	

**Section 2: Participating ASCs and providers** 

Baltimore County	
Surgcenter of White Marsh* 11605 Crossroads Circle, Suites A-C Baltimore, MD 21220	SurgiCenter of Baltimore 23 Crossroads Drive, Suite 100 Owings Mills, MD 21117
Timonium Surgery Center, LLC* 1954 Greenspring Drive, Suite LL18 Lutherville-Timonium, MD 21093	White Marsh Surgery Center 4924 Campbell Blvd. Nottingham, MD 21236
York Green Surgery Center LLC 1300 York Road, Suite 200 Lutherville-Timonium, MD 21093	
Howard County	
Ellicott City Ambulatory Surgery Center 2850 N. Ridge Road Ellicott City, MD 21043	University of MD Medicine Ambulatory Surgery Center 5900 Waterloo Road, Suite 120 Columbia, MD 21045
<b>Maple Lawn ASC*</b> 7625 Maple Lawn Blvd., Suite 110 Fulton, MD 20759	Maryland Surgeons Center of Columbia 11055 Little Patuxent Parkway, Suite L6 Columbia, MD 21044
Montgomery County	
Montgomery Surgery Center* 46 W. Gude Drive Rockville, MD 20850	Quince Orchard Surgery Center* 900 Wind River Lane, Suite 106 Gaithersburg, MD 20878
SurgCenter of Silver Spring LLC 8710 Cameron St., Suite 100 Silver Spring, MD 20910	Capital Women's Care Specialty 11400 Rockville Pike, Suite C25 Rockville, MD 20852
Prince George's County	
Forbes Ambulatory Surgery Center* 7501 Forbes Blvd., Suite 103 Lanham, MD 20706	Dimensions Healthcare System 14999 Health Center Drive Bowie, MD 20716
Surgcenter of Greenbelt LLC 7300 Hanover Drive, Suite 102 Greenbelt, MD 20770	University Center for Ambulatory Surgery 6502 Kenilworth Ave., Suite 200 Riverdale, MD 20737
SurgCenter of Southern Maryland LLC 9001 Woodyard Road, Suite B Clinton, MD 20735	

<sup>\*</sup> Privately owned ASC.

#### **Outpatient GYN precertification initiative**

Amerigroup Community Care requires outpatient GYN procedures and surgeries to be provided at an ambulatory surgery center (ASC) or provider office unless precertified at a hospital in the following counties: Baltimore City, Baltimore County, Howard County, Montgomery County and Prince George's County. Effective March 1, 2019, only the services that cannot be provided safely and effectively at a freestanding ASC or office will be approved to be performed at the hospital.

#### What is the impact of this change?

Unless there is a medical reason for providing the outpatient GYN procedures and surgeries listed on the provided code list in a hospital, the services must be performed at a freestanding ASC or in an office. Members who are 18 years of age or younger are excluded from this initiative.

Providers should review Section 1 of this communication for a list of procedure codes that will require precertification to be performed in a hospital. For code-specific precertification requirements, please refer to https://providers.amerigroup.com/MD > Provider Resources & Documents > Quick Tools > select Precertification Lookup Tool.

Providers should review Section 2 for a list of participating ASCs that offer GYN services.

This initiative applies to providers in Baltimore City, Baltimore County, Howard County, Montgomery County and Prince George's County and covers all GYN codes listed on our provider website.

#### How do I obtain precertification?

You must call Provider Services at 1-800-454-3730 and provide clinical documentation showing a medical reason why the member needs to have an outpatient GYN procedure done in a hospital.

#### What if I need assistance?

If you have questions about this communication or need assistance with any other item, contact your local Provider Relations representative or call Provider Services at 1-800-454-3730.

Thank you for the quality care you provide to our members.

<sup>\*</sup> Participating provider listings change periodically. For the latest list of participating ASCs offering services, see our provider directory at https://providers.amerigroup.com/MD or call Provider Services at 1-800-454-3730 to find the facility most convenient for your patient.

#### Medical necessity criteria

List of relevant case or member-specific facts that support the use of hospital-based or regulated space procedures. Reasons may include but are not limited to:

- Ability of a freestanding site of service to safely and adequately accommodate and support the member in the course of treatment because of specialized equipment or staff skill set
- Access or availability of a freestanding site of service within the 30-minute or 30-mile standard
- Member is 18 years of age or younger
- Suffering from any of the following conditions:
  - Respiratory disease
    - Asthma
    - Chronic obstructive pulmonary disease/emphysema
    - Sleep apnea and actively using continuous positive airway pressure
  - Cardiac disease
    - Congestive heart failure symptomatic in the last month (any episode of documented or active congestive heart failure, emergency room visit, admission, worsening chronic congestive heart failure, recent adjustment of medicines, etc.)
    - Myocardial infarction within the last six weeks
    - Arrhythmia within the last six weeks
    - Pacemaker in place
    - Automatic implantable cardioverter defibrillator in place
    - On warfarin or another anticoagulant
    - On Plavix® or another platelet inhibitor
- Severe anemia/hematocrit < 25%, platelets < 30,000</li>
- Morbid obesity/body mass index > 40
- History of any complication with sedation, anesthesia or surgery

#### Section 1: Procedure codes required for precertification in a hospital

The following procedure codes will require precertification to be performed in a hospital. Providers must provide a medical reason why the procedure must be performed in a hospital setting.

Procedures performed in association with an ER visit or associated with an outpatient surgery performed at a hospital on the same day will not require precertification.

Procedure code	Procedure description
57500	Biopsy of cervix, single or multiple, or local excision of lesion, with or without fulguration (separate procedure)
57505	Endocervical Curettage (not done as part of a dilation & curettage)
57510	Cauterization, Cervix; Electro/Thermal
57513	Cauterization, Cervix; Laser Ablation
57520	Conization, Cervix W/Wo Fulguration, W/Wo D&C/Repair; Cold Knife/Laser

Procedure code	Procedure description
57522	Conization, Cervix W/Wo Fulguration, W/Wo D&C/Repair; Loop
58100	Endometrial Bx W/Wo Endocervical Bx, W/O Dilation, Any Method (separate procedure)
58120	Dilation & Curettage, Dx &/Or Therapeutic (nonobstetrical)
58555	Hysteroscopy, Dx (separate procedure)
58558	Hysteroscopy, Surgical; W/Endometrial Bx &/Or Polypectomy W/Wo D&C
58560	Hysteroscopy, Surgical; W/Division/Resection Intrauterine Septum, Any Method
58561	Hysteroscopy, Surgical; W/Removal Leiomyomata
58562	Hysteroscopy, Surgical, W/Removal Impacted Fb
58563	Hysteroscopy, Surgical; W/Endometrial Ablation
58565	Hysteroscopy, surgical; with bilateral fallopian tube cannulation to induce occlusion by placement of permanent implants
57500	Biopsy of cervix, single or multiple, or local excision of lesion, with or without fulguration (separate procedure)
57505	Endocervical Curettage (not done as part of a dilation & curettage)
57510	Cauterization, Cervix; Electro/Thermal
57513	Cauterization, Cervix; Laser Ablation
57520	Conization, Cervix W/Wo Fulguration, W/Wo D&C/Repair; Cold Knife/Laser
57522	Conization, Cervix W/Wo Fulguration, W/Wo D&C/Repair; Loop
58100	Endometrial Bx W/Wo Endocervical Bx, W/O Dilation, Any Method (separate procedure)
58120	Dilation & Curettage, Dx &/Or Therapeutic (nonobstetrical)
58555	Hysteroscopy, Dx (separate procedure)
58558	Hysteroscopy, Surgical; W/Endometrial Bx &/Or Polypectomy W/Wo D&C
58560	Hysteroscopy, Surgical; W/Division/Resection Intrauterine Septum, Any Method
58561	Hysteroscopy, Surgical; W/Removal Leiomyomata
58562	Hysteroscopy, Surgical, W/Removal Impacted Fb

Procedure code	Procedure description
58563	Hysteroscopy, Surgical; W/Endometrial Ablation
58565	Hysteroscopy, surgical; with bilateral fallopian tube cannulation to induce occlusion by placement of permanent implants

#### **Section 2: Participating ASCs and providers**

Baltimore City			
University of Maryland Surgical 419 W. Redwood St. Baltimore, MD 21201			
Baltimore County			
Surgcenter of White Marsh* 11605 Crossroads Circle, Suites A-C Baltimore, MD 21220-2865	Timonium Surgery Center 1954 Greenspring Drive, Suite LL18 Lutherville-Timonium, MD 21093-4111		
Towson Surgical Center 1122 Kenilworth Drive, Suite 17 Towson, MD 21204-2151	White Marsh Surgery Center 4924 Campbell Blvd. Nottingham, MD 21236-5908		
SurgiCenter of Baltimore 23 Crossroads Drive, Suite 100 Owings Mills, MD 21117			
Howard County			
Ellicott City Ambulatory Surgery Center 2850 N. Ridge Road Ellicott City, MD 21043-3464	University of Maryland Ambulatory Surgery Center 5900 Waterloo Road, Suite 120 Columbia, MD 21045-2636		
Montgomery County			
Congressional Ambulatory Surgery Center* 15005 Shady Grove Road, Suite 130 Rockville, MD 20850-6341	Maryland Surgery Center for Women 11400 Rockville Pike, Suite C25 Rockville, MD 20852-3063		
Montgomery Surgery Center 46 W. Gude Drive Rockville, MD 20850			
Prince George's County			
Advantia Health Indian Creek Ambulatory Surgery Center* 12240 Indian Creek Court, Suite 130 Beltsville, MD 20705-1260	Forbes Ambulatory Surgery Center 7501 Forbes Blvd., Suite 103 Lanham, MD 20706-6201		

<sup>\*</sup> Privately owned ASC.





## SITE OF SERVICE GUIDELINES FOR CERTAIN OUTPATIENT SURGICAL PROCEDURES

**Guideline Number**: URG-11.02 **Effective Date**: January 1, 2018

Table of Contents	Page
INSTRUCTIONS FOR USE	1
BENEFIT CONSIDERATIONS	1
COVERAGE RATIONALE	1
DEFINITIONS	
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GUIDELINE HISTORY/REVISION INFORMATION	

#### Related Commercial Policy

• Obstructive Sleep Apnea Treatment

#### Community Plan Policy

• <u>Site of Service Guidelines for Certain Outpatient</u> Surgical Procedures

#### INSTRUCTIONS FOR USE

This Utilization Review Guideline provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the member specific benefit plan document must be referenced. The terms of the member specific benefit plan document [e.g., Certificate of Coverage (COC), Schedule of Benefits (SOB), and/or Summary Plan Description (SPD)] may differ greatly from the standard benefit plan upon which this Utilization Review Guideline is based. In the event of a conflict, the member specific benefit plan document supersedes this Utilization Review Guideline. All reviewers must first identify member eligibility, any federal or state regulatory requirements, and the member specific benefit plan coverage prior to use of this Utilization Review Guideline. Other Policies and Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary. This Utilization Review Guideline is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the  $MCG^{TM}$  Care Guidelines, to assist us in administering health benefits. The  $MCG^{TM}$  Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

#### BENEFIT CONSIDERATIONS

Before using this guideline, please check the member specific benefit plan document and any federal or state mandates, if applicable.

These prior authorization requirements apply to UnitedHealthcare commercial plans that require services to be medically necessary, including being cost-effective. Refer to the member specific benefit plan document to determine if medical necessity applies.

#### **Essential Health Benefits for Individual and Small Group**

For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs"). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs, the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this guideline, it is important to refer to the member specific benefit plan document to determine benefit coverage.

#### COVERAGE RATIONALE

With the exception of the qualifying conditions below, certain elective procedures should be performed in an Ambulatory Surgical Center (ASC).

Effective 01/01/2018

The following will be taken into account to determine whether the elective procedure is being performed in a cost effective setting:

- Member's specific benefit plan
- Geographic availability of an in network provider
- Ambulatory surgical care (ASC) capability
- Physician privileging
- Significant member comorbidities (see list of examples of Qualifying Conditions below)
- American Society of Anesthesiologist (ASA) physical status (PS), classification system

#### Potential Documentation Requirements

- Physician office notes
- Physician privileging
- ASA score

#### Certain Qualifying Conditions

Some patients may require more complex care due to factors such as age or medical conditions. Also, some ASCs may have specific guidelines that prohibit members who are above a certain weight or have certain health conditions from receiving care in those facilities.

Patients with severe systemic disease and some functional limitation (ASA PS classification III or higher) may be appropriate to have the procedure in an outpatient hospital setting (not an all-inclusive list):

- Morbid obesity (>BMI.40)
- Diabetes (brittle diabetes)
- Resistant hypertension (poorly controlled)
- Chronic obstructive pulmonary disease (COPD) (FEV1 < 50%)
- Advance liver disease (MELD Score > 8)
- Alcohol dependence (at risk for withdrawal syndrome)
- End stage renal disease (hyperkalemia (above reference range peritoneal or hemodialysis)
- Uncompensated chronic heart failure (CHF) (NYHA class III or IV)
- History of myocardial infarction (MI) (recent event (< 3 mo.))
- History of cerebrovascular accident (CVA) or transient ischemic attack (TIA) (recent event (< 3 mo.))
- Coronary artery disease (CAD/peripheral vascular disease (PVD) (ongoing cardiac ischemia requiring medical management recently placed drug eluting stent (within 1 year))
- Sleep apnea (moderate to severe obstructive sleep apnea (OSA)
- Implanted pacemaker
- Personal history or family history of complication of anesthesia such as malignant hyperthermia
- Bleeding disorder requiring replacement factor or blood products or special infusion products to correct a coagulation defect (DDAVP is not blood product and is OK)
- Prolonged surgery (>3 hrs.)
- Anticipated need for transfusion
- Recent history of drug abuse (especially cocaine)
- Patients with drug eluting stents (DES) placed within one year or bare metal stents (BMS) or plain angioplasty within 90 days unless acetylsalicylic acid (ASA) and antiplatelet drugs will be continued by agreement of surgeon, cardiologist and anesthesia
- Ongoing evidence of myocardial ischemia
- Poorly controlled asthma (FEV1 < 80% despite medical management)
- Significant valvular heart disease
- Cardiac arrhythmia (symptomatic arrhythmia despite medication)

#### **Elective Procedures List**

Prior authorization is required for the following procedures if performed in an outpatient hospital setting (see Applicable Codes table).

#### DEFINITIONS

ASA Physical Status Classification System Risk Scoring Tool: While anesthesia providers use this scale to indicate one's overall physical health or "sickness" preoperatively, it is regarded by hospitals, law firms, accrediting boards and other healthcare groups as a scale to predict risk and thus decide if a patient should have or should have had an operation. To predict operative risk, age and obesity, the nature and severity of the operative procedure, selection of anesthetic techniques, the competency of the surgical team (surgeon, anesthesia providers and assisting staff), duration of surgery or anesthesia, availability of equipment, medicine, blood, implants and especially the level of post-operative care etc. are often far more important than multiple ASA classification.

> Effective 01/01/2018

**Brittle Diabetes:** Diabetes that is difficult to control due to symptoms such as (1) predominant hyperglycemia with recurrent ketoacidosis, (2) predominant hypoglycemia, and (3) mixed hyper- and hypoglycemia.

**Obstructive Sleep apnea (OSA)**: Severity is defined as: Moderate for AHI or RDI  $\geq$  15 and  $\leq$  30. Severe for AHI or RDI > 30/hr.

**Poorly Controlled:** Requiring three or more drugs to control blood pressure.

#### APPLICABLE CODES

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not imply that the service described by the code is a covered or noncovered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or quarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
Carpal Tunnel Surgery	
64721	Neuroplasty and/or transposition; median nerve at carpal tunnel
Cataract Surgery	
66821	Discission of secondary membranous cataract (opacified posterior lens capsule and/or anterior hyaloid); laser surgery (e.g., YAG laser) (1 or more stages)
66982	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (e.g., iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage
66984	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification)
Cosmetic & Reconstruct	ve
13101	Repair, complex, trunk; 2.6 cm to 7.5 cm
13132	Repair, complex, forehead, cheeks, chin, mouth, neck, axillae, genitalia, hands and/or feet; 2.6 cm to 7.5 cm
14040	Adjacent tissue transfer or rearrangement, forehead, cheeks, chin, mouth, neck, axillae, genitalia, hands and/or feet; defect 10 sq cm or less
14060	Adjacent tissue transfer or rearrangement, eyelids, nose, ears and/or lips; defect 10 sq cm or less
14301	Adjacent tissue transfer or rearrangement, any area; defect 30.1 sq cm to 60.0 sq cm
21552	Excision, tumor, soft tissue of neck or anterior thorax, subcutaneous; 3 cm or greater
21931	Excision, tumor, soft tissue of back or flank, subcutaneous; 3 cm or greater
ENT Procedures	
21320	Closed treatment of nasal bone fracture; with stabilization
30140	Submucous resection inferior turbinate, partial or complete, any method
30520	Septoplasty or submucous resection, with or without cartilage scoring, contouring or replacement with graft
69436	Tympanostomy (requiring insertion of ventilating tube), general anesthesia
69631	Tympanoplasty without mastoidectomy (including canalplasty, atticotomy and/or middle ear surgery), initial or revision; without ossicular chain reconstruction
<b>Gynecologic Procedures</b>	
57522	Conization of cervix, with or without fulguration, with or without dilation and curettage, with or without repair; loop electrode excision
58353	Endometrial ablation, thermal, without hysteroscopic guidance
	Effective

CPT Code	Description
Gynecologic Procedures	
58558	Hysteroscopy, surgical; with sampling (biopsy) of endometrium and/or polypectomy, with or without D $\&$ C
58563	Hysteroscopy, surgical; with endometrial ablation (e.g., endometrial resection, electrosurgical ablation, thermoablation)
58565	Hysteroscopy, surgical; with bilateral fallopian tube cannulation to induce occlusion by placement of permanent implants
Hernia	
49505	Repair initial inguinal hernia, age 5 years or older; reducible
49585	Repair umbilical hernia, age 5 years or older; reducible
49587	Repair umbilical hernia, age 5 years or older; incarcerated or strangulated
49650	Laparoscopy, surgical; repair initial inguinal hernia
49651	Laparoscopy, surgical; repair recurrent inguinal hernia
49652	Laparoscopy, surgical, repair, ventral, umbilical, spigelian or epigastric hernia (includes mesh insertion, when performed); reducible
49653	Laparoscopy, surgical, repair, ventral, umbilical, spigelian or epigastric hernia (includes mesh insertion, when performed); incarcerated or strangulated
49654	Laparoscopy, surgical, repair, incisional hernia (includes mesh insertion, when performed); reducible
49655	Laparoscopy, surgical, repair, incisional hernia (includes mesh insertion, when performed); incarcerated or strangulated
Liver Biopsy	
47000	Biopsy of liver, needle; percutaneous
Miscellaneous	
20680	Removal of implant; deep (e.g., buried wire, pin, screw, metal band, nail, rod or plate)
Ophthalmologic	
65426	Excision or transposition of pterygium; with graft
65730	Keratoplasty (corneal transplant); penetrating (except in aphakia or pseudophakia)
65855	Trabeculoplasty by laser surgery
66170	Fistulization of sclera for glaucoma; trabeculectomy ab externo in absence of previous surgery
66761	Iridotomy/iridectomy by laser surgery (e.g., for glaucoma) (per session)
67028	Intravitreal injection of a pharmacologic agent (separate procedure)
67036	Vitrectomy, mechanical, pars plana approach
67040	Vitrectomy, mechanical, pars plana approach; with endolaser panretinal photocoagulation
67228	Treatment of extensive or progressive retinopathy (e.g., diabetic retinopathy), photocoagulation
67311	Strabismus surgery, recession or resection procedure; 1 horizontal muscle
67312	Strabismus surgery, recession or resection procedure; 2 horizontal muscles
Tonsillectomy & Adenector	ny
42820	Tonsillectomy and adenoidectomy; younger than age 12
42821	Tonsillectomy and adenoidectomy; age 12 or over
42825	Tonsillectomy, primary or secondary; younger than age 12
42826	Tonsillectomy, primary or secondary; age 12 or over
42830	Adenoidectomy, primary; younger than age 12
<b>Upper &amp; Lower Gastrointes</b>	tinal Endoscopy
43235	Esophagogastroduodenoscopy, flexible, transoral; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)

CPT Code	Description
<b>Upper &amp; Lower Gastrointes</b>	tinal Endoscopy
43239	Esophagogastroduodenoscopy, flexible, transoral; with biopsy, single or multiple
43249	Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic balloon dilation of esophagus (less than 30 mm diameter)
45378	Colonoscopy, flexible; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure)
45380	Colonoscopy, flexible; with biopsy, single or multiple
45384	Colonoscopy, flexible; with removal of tumor(s), polyp(s), or other lesion(s) by hot biopsy forceps
45385	Colonoscopy, flexible; with removal of tumor(s), polyp(s), or other lesion(s) by snare technique
Urology	
50590	Lithotripsy, extracorporeal shock wave
52000	Cystourethroscopy (separate procedure)
52005	Cystourethroscopy, with ureteral catheterization, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service;
52204	Cystourethroscopy, with biopsy(s)
52224	Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) or treatment of MINOR (less than 0.5 cm) lesion(s) with or without biopsy
52234	Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) and/or resection of; SMALL bladder tumor(s) (0.5 up to 2.0 cm)
52235	Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) and/or resection of; MEDIUM bladder tumor(s) (2.0 to 5.0 cm)
52260	Cystourethroscopy, with dilation of bladder for interstitial cystitis; general or conduction (spinal) anesthesia
52281	Cystourethroscopy, with calibration and/or dilation of urethral stricture or stenosis, with or without meatotomy, with or without injection procedure for cystography, male or female
52310	Cystourethroscopy, with removal of foreign body, calculus, or ureteral stent from urethra or bladder (separate procedure); simple
52332	Cystourethroscopy, with insertion of indwelling ureteral stent (e.g., Gibbons or double-J type)
52351	Cystourethroscopy, with ureteroscopy and/or pyeloscopy; diagnostic
52352	Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with removal or manipulation of calculus (ureteral catheterization is included)
52353	Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with lithotripsy (ureteral catheterization is included)
52356	Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with lithotripsy including insertion of indwelling ureteral stent (e.g., Gibbons or double-J type)
54161	Circumcision, surgical excision other than clamp, device, or dorsal slit; older than 28 days of age
55040	Excision of hydrocele; unilateral
55700	Biopsy, prostate; needle or punch, single or multiple, any approach
57288	Sling operation for stress incontinence (e.g., fascia or synthetic)
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#### DESCRIPTION OF SERVICES

In an effort to minimize out-of-pocket costs for UnitedHealthCare members and to improve cost efficiencies for the overall health care system, we are implementing prior authorization guidelines that aim to encourage more cost-effective sites of service for certain outpatient surgical procedures, when medically appropriate.

Effective 01/01/2018

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#### GUIDELINE HISTORY/REVISION INFORMATION

Date	Action/Description
01/01/2018	<ul> <li>Reformatted and reorganized policy; transferred content to new template</li> <li>Revised coverage rationale:         <ul> <li>Removed footnotes pertaining to clinical descriptions/definitions from list of examples of Certain Qualifying Conditions</li> <li>Updated list of services requiring prior authorization in the outpatient hospital setting; removed abdominal paracentesis (CPT code 49083)</li> </ul> </li> <li>Modified definition of:         <ul> <li>Brittle Diabetes</li> <li>Obstructive Sleep Apnea (OSA)</li> <li>Poorly Controlled</li> </ul> </li> <li>Updated list of CPT codes requiring prior authorization in the outpatient hospital setting; removed 49083</li> <li>Updated supporting information to reflect the most current references</li> <li>Archived previous policy version URG-11.01</li> </ul>

# Exhibit CQ1.5A



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I hereby declare and affirm under the penalties of perjury that the facts stated in this application and its attachments are true and correct to the best of my knowledge, information, and belief.

Anne Langley

Senior Director

Health Planning and Community Engagement

Johns Hopkins Health System

16 May 2019 Date

I hereby declare and affirm under the penalties of perjury that the facts stated in this application and its attachments are true and correct to the best of my knowledge, information, and belief.

Spencer Wildonger

Director of Health Planning

Health Care Transformation & Strategic Planning

Johns Hopkins Health System

 $\frac{5/15/2619}{\text{Date}}$ 

I hereby declare	and affirm unde	er the penalties	s of perjury	that the facts	s stated in thi	s application
and its attachmen	nts are true and	correct to the	best of my l	knowledge, i	nformation, a	and belief.

Tyler Dunn Administrative Resident

I hereby declare and affirm under the penalties of perjury that the facts stated in response to question 4 of these completeness questions and its attachments are true and correct to the best of my knowledge, information, and belief.

Lisa Ogorzalek

Vice President of Managed Care Johns Hopkins Health Care 5/16//9 Date

I hereby declare and affirm under the penalties of perjury that the facts stated in this application and its attachments are true and correct to the best of my knowledge, information, and belief.

Philip J. Lange, CPA
Lange & Associates, LLC

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5-15-19 Date