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The following list of outpatient medications covered under Medicare Part B (i.e., drugs that are delivered in the physician's office, clinic, outpatient, or home setting) require preauthorization prior to being provided or administered. This list does not include drugs that process under the Medicare Part D pharmacy benefit, such as self-administered drugs or oral medications. Coverage will be provided for Part B medical drugs when it is determined to be medically necessary, in accordance with Centers for Medicare & Medicaid Services (CMS) guidelines (Available at: <a href="http://www.cms.gov/medicare-coverage-database">http://www.cms.gov/medicare-coverage-database</a>).

Coverage of these outpatient medications is based on existing National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs), and other relevant sources. Adherence to these policies is required when they exist. The table below lists drug names, HCPCS codes, applicable Medicare policies, and \*Step Therapy Program requirements. For drugs, which do not have an applicable NCD, LCD, or LCA, there may be a clinical resource. In the absence of Medicare coverage guidance (NCDs, LCDs, etc.), CMS allows Medicare Advantage plans to implement their criteria for coverage with the guidance and review of a Drug Committee. Please refer to the published clinical policy on Aspire Health's website under Part B drugs.

\*Some Part B drugs may also require **step therapy** before they will be covered. Prior authorization will be required in these cases. Contraindication, intolerance, or a prior trial and failure with a preferred drug in the same class or category may be required, amongst other criteria. Step therapy is required when indicated in the 'Step Therapy Program' column of the table below.

This list is subject to change. Please review this list periodically for updates. Aspire Health Plan reserves the right to revise, update, and/or add/remove drugs as new drugs are FDA-approved and become available for use.

ANTI-AMYLOID AGENTS (ALZHEIMER DISEASE)				
Drug Name	HCPCS	Medicare Policies (NCD, LCD, LCA)	Clinical Resource for Drugs without NCD/ LCD/LCA	Step Therapy Program
Leqembi (lecanemab-irmb)	J0174	<u>NCD</u>	Aspire Clinical Policy	No
Aduhelm (aducanumab)	J0172	<u>NCD</u>	Aspire Clinical Policy	No

NEUROMUSCULAR BLOCKERS					
Drug Name	HCPCS	Medicare Policies (NCD, LCD, LCA)	Clinical Resource for Drugs without NCD/ LCD/LCA	Step Therapy Program	
Botox (onabotulinumtoxin)	J0585	Noridian JE Part B LCD (L35170)	Aspire Clinical Policy (in accordance with LCD L35170)	No	
Dysport (abobotulinumtoxin A)	J0586	Noridian JE Part B LCD (L35170)	Aspire Clinical Policy (in accordance with LCD L35170)	No	
Myobloc (rimabotulinumtoxin B)	J0587	Noridian JE Part B LCD (L35170)	Aspire Clinical Policy (in accordance with LCD L35170)	No	
Xeomin (incobotulinumtoxin A)	J0588	Noridian JE Part B LCD (L35170)	Aspire Clinical Policy (in accordance with LCD L35170)	No	

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Injection, daxibotulinumtoxinA-lanm, 1 unit	10589	Noridian JE Part B	Aspire Clinical Policy	No
(Daxxify)	30369	LCD (L35170)	(in accordance with LCD L35170)	No

BONE DENSITY AGENTS (OSTEOPOROSIS)					
Drug Name	HCPCS	Medicare Policies (NCD, LCD, LCA)	Clinical Resource for Drugs without NCD/ LCD/LCA	Step Therapy Program	
Bisphosphonates (IV):      Zoledronic acid (Reclast)     Ibandronate (Boniva)	J3489 J1740		No PA required	No	
Prolia (denosumab)	J0897		Aspire Clinical Policy	Yes	
Jubbonti (denosumab-bbdz) Biosimilar to Prolia	J3590		Aspire Clinical Policy	Yes	
Xgeva (denosumab)	J0897		Aspire Clinical Policy	Yes	
Wyost (denosumab-bbdz) Biosimilar to Xgeva	C9399 J3490 J3590 J9999		Aspire Clinical Policy	Yes	
Evenity (romosozumab)	J3111		Aspire Clinical Policy	Yes	

GONADOTROPIN RE	GONADOTROPIN RELEASING HORMONE ANALOGS (ONCOLOGY; WOMEN'S HEALTH INDICATIONS)					
Drug Name	HCPCS	Medicare Policies (NCD, LCD, LCA)	Clinical Resource for Drugs without NCD/ LCD/LCA	Step Therapy Program		
Lupron Depot 1-Month 3.75 mg Lupron Depot 3-Month 11.25 mg	J1950		Aspire Clinical Policy	No		
Camcevi 42 mg Kit	J1952		Aspire Clinical Policy	No		
Lupron Depot 1-Month & Eligard 7.5 mg Lupron Depot 3-Month & Eligard 22.5 mg Lupron Depot 4-Month & Eligard 30 mg Lupron Depot 6-Month & Eligard 45 mg	J9217		Aspire Clinical Policy	No		
Lutrate Depot 22.5 mg Kit 3-Month	J1954		Aspire Clinical Policy	No		

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INTRA-ARTICULAR CORTICOSTEROIDS (OSTEOARTHRITIS)						
Drug Name	HCPCS	Medicare Policies (NCD, LCD, LCA)	Clinical Resource for Drugs without NCD/ LCD/LCA	Step Therapy Program		
Methylprednisolone acetate injection (Depo-Medrol) Methylprednisolone sodium succinate, injection (Solumedrol)	J1010 J2919		No PA required	No		
Triamcinolone acetonide injection (Kenalog) Triamcinolone diacetate injection Triamcinolone hexacetonide injection	J3301 J3302 J3303		No PA required	No		
Zilretta (triamcinolone acetonide ER)	J3304		Aspire Clinical Policy	Yes		
HYALUR	ONIC ACIDS	/ VISCOSUPPLEMENTS (OS	TEOARTHRITIS)			
Drug Name	HCPCS	Medicare Policies (NCD, LCD, LCA)	Clinical Resource for Drugs without NCD/ LCD/LCA	Step Therapy Program		
Durolane	J7318		Aspire Clinical Policy	Yes		
Gel-One	J7326		Aspire Clinical Policy	Yes		
Monovisc	J7327		Aspire Clinical Policy	Yes		
Synvisc-One	J7325		Aspire Clinical Policy	Yes		
VISCO-3	J7321		Aspire Clinical Policy	Yes		
Euflexxa	J7323		Aspire Clinical Policy	Yes		
GelSyn-3	J7328		Aspire Clinical Policy	Yes		
Hyalgan, Supartz, Supartz FX,	J7321		Aspire Clinical Policy	Yes		
GenVisc 850	J7320		Aspire Clinical Policy	Yes		
Hymovis	J7322		Aspire Clinical Policy	Yes		
Orthovisc	J7324		Aspire Clinical Policy	Yes		
Synojoynt	J7331		Aspire Clinical Policy	Yes		
Synvisc	J7325		Aspire Clinical Policy	Yes		
Triluron	J7332		Aspire Clinical Policy	Yes		

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MULTIPLE SCLEROSIS (INFUSION)					
Drug Name	HCPCS	Medicare Policies (NCD, LCD, LCA)	Clinical Resource for Drugs without NCD/ LCD/LCA	Step Therapy Program	
Tysabri (natalizumab)	J2323		Aspire Clinical Policy	Yes	
Ocrevus (ocrelizumab)	J2350		Aspire Clinical Policy	Yes	
Lemtrada (alemtuzumab)	J0202		Aspire Clinical Policy	Yes	

ONCOLOGY DRUGS					
Drug Name	HCPCS	Medicare Policies (NCD, LCD, LCA)	Clinical Resource for Drugs without NCD/ LCD/LCA	Step Therapy Program	
Keytruda (pembrolizumab)	J9271		Aspire Clinical Policy	No	
Tecentriq (atezolizumab)	J9022		Aspire Clinical Policy	No	

		BIOSIMILARS				
	INFLIXIMAB PRODUCTS					
Drug Name	HCPCS	Medicare Policies (NCD, LCD, LCA)	Clinical Resource for Drugs without NCD/ LCD/LCA	Step Therapy Program		
Remicade (infliximab)	J1745		Aspire Clinical Policy	Yes		
Infliximab	J1745		Aspire Clinical Policy	Yes		
Inflectra (infliximab-dyyb)	Q5103		Aspire Clinical Policy	Yes		
Avsola (infliximab-axxq)	Q5121		Aspire Clinical Policy	Yes		
Renflexis (infliximab-abda)	Q5104		Aspire Clinical Policy	Yes		
Zymfentra (infliximab-dyyb)	J3590 Q5136		Aspire Clinical Policy	Yes		
		RITUXIMAB PRODUCTS				
Rituxan (rituximab)	J9312		Aspire Clinical Policy	Yes		
Rituxan Hycela (rituximab and hyaluronidase)	J9311		Aspire Clinical Policy	Yes		
Ruxience (rituximab-pvvr)	Q5119		Aspire Clinical Policy	Yes		
Truxima (rituximab-abbs)	Q5115		Aspire Clinical Policy	Yes		
Riabni (rituximab-arrx)	Q5123		Aspire Clinical Policy	Yes		

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ONCOLOGY BIOSIMILARS							
BEVACIZ	BEVACIZUMAB PRODUCTS (ONCOLOGY ONLY; NOT APPLICABLE TO OPTHALMOLOGY)						
Drug Name	HCPCS	Medicare Policies (NCD, LCD, LCA)	Clinical Resource for Drugs without NCD/ LCD/LCA	Step Therapy Program			
Avastin (bevacizumab)	J9035		Aspire Clinical Policy	No			
Alymsys (bevacizumab-maly), biosimilar	Q5126		Aspire Clinical Policy	No			
Mvasi (bevacizumab-awwb), biosimilar	Q5107	For Colorectal diagnosis: Refer to NCD 110.17:	Aspire Clinical Policy	No			
Vegzelma (bevacizumab-adcd), biosimilar)	Q5129	Anti-Cancer Chemotherapy for	Aspire Clinical Policy	No			
Zirabev (bevacizumab-bvzr), biosimilar	Q5118	Colorectal Cancer	Aspire Clinical Policy	No			
Avzivi (bevacizumab-tnjn)	C9399 J9999		Aspire Clinical Policy	No			
		TRASTUZUMAB PRODUCTS					
Herceptin (trastuzumab); excludes biosimilars	J9355		Aspire Clinical Policy	No			
Herceptin Hylecta (trastuzumab and hyaluronidase-oysk)	J9356		Aspire Clinical Policy	No			
Enhertu (fam-trastuzumab deruxtecan-nxki)	J9358		Aspire Clinical Policy	No			
Ontruzant (trastuzumab-dttb), biosimilar	Q5112		Aspire Clinical Policy	No			
Herzuma (trastuzumab-pkrb), biosimilar	Q5113		Aspire Clinical Policy	No			
Ogivri (trastuzumab-dkst), biosimilar	Q5114		Aspire Clinical Policy	No			
Trazimera (trastuzumab-qyyp), biosimilar	Q5116		Aspire Clinical Policy	No			
Kanjinti (trastuzumab-anns), biosimilar	Q5117		Aspire Clinical Policy	No			
Phesgo (pertuzumab, trastuzumab, hyaluronidase-zzxf)	J9316		Aspire Clinical Policy	No			

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THYROID EYE DISEASE					
Drug Name	HCPCS	Medicare Policies (NCD, LCD, LCA)	Clinical Resource for Drugs without NCD/ LCD/LCA	Step Therapy Program	
Tepezza (teprotumumab-trbw)	J3241		Aspire Clinical Policy	No	

UNLISTED DRUGS AND BIOLOGICALS					
Drug Name	HCPCS	Medicare Policies (NCD, LCD, LCA)	Clinical Resource for Drugs without NCD/ LCD/LCA	Step Therapy Program	
Unclassified drugs or biologicals	C9399		Aspire Clinical Policy	No	
Unclassified drugs	J3490		Aspire Clinical Policy	No	
Unclassified biologics	J3590		Aspire Clinical Policy	No	
Unclassified drug or biological used for ESRD on dialysis	J3591		Aspire Clinical Policy	No	
Hemophilia clotting factor, not otherwise classified	J7199		Aspire Clinical Policy	No	

VASCULAR ENDOTHELIAL GROWTH FACTOR (VEGF) INHIBITOR (RETINAL DISORDERS AGENTS)				
Drug Name	HCPCS	Medicare Policies (NCD, LCD, LCA)	Clinical Resource for Drugs without NCD/ LCD/LCA	Step Therapy Program
Avastin (bevacizumab)	C9257 J7999		No PA required	No
*Eylea (aflibercept)	J0178		Aspire Clinical Policy	Yes (*exceptions apply)
Eylea HD (aflibercept)	J0177		Aspire Clinical Policy	Yes
Lucentis (ranibizumab)	J2778		Aspire Clinical Policy	Yes
Byooviz (ranibizumab-nuna)	Q5124		Aspire Clinical Policy	Yes
Cimerli (ranibizumab-eqrn)	J3590		Aspire Clinical Policy	Yes
Susvimo (ranibizumab implant)	J2779		Aspire Clinical Policy	Yes
Beovu (brolucizumab-dbll)	J0179		Aspire Clinical Policy	Yes
Vabysmo (faricimab)	J2777		Aspire Clinical Policy	Yes

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Medicare covers outpatient (Part B) drugs that are furnished "incident to" a physician's service provided that the drugs are not usually self- administered by the patients who take them. See the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals at: http://www.cms.hhs.gov/manuals/Downloads/bp102c15.pdf.

This Medicare Part B Prior Authorization Drug List is provided for informational purposes only and neither constitutes nor replaces professional medical advice. Physicians, hospitals, and other providers are expected to administer or use drugs/biologicals in the most effective and clinically appropriate manner. Treating physicians and other health care providers is solely responsible for all medical care decisions. In accordance with the member's Evidence of Coverage (EOC), every benefit plan has its own coverage provisions, limitations, and exclusions. In the event of a conflict between this policy and the member's EOC, the member's EOC provisions will take precedence.

The inclusion of a code in this policy does not imply that the health service it describes is covered or not covered. Benefit coverage for health services is determined by the member-specific plan document and applicable laws that may mandate coverage for a particular service. Inclusion of a code does not imply or guarantee reimbursement or payment of a claim. Other Policies and Standards may also apply. Providers are expected to retain or have access to the necessary documentation when requested to support coverage.

#### References

- 1. Medicare Managed Care Manual, Chapter 4, §90.5.
- 2. Centers for Medicare and Medicaid Services, Medicare Advantage Prior Authorization and Step Therapy for Part B Drugs. August 7, 2018. Available online at: http://cms.gov.
- 3. Centers for Medicare and Medicaid Services, Internet-Only Medicare Benefit Policy Manual, CMS Pub. 100-02, Chapter 15, Sec. 50. Available online at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs.



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