Gel-One® Cross-Linked Hyaluronate Coding Reference Guide

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Gel-One Hyaluronate is an injectable hyaluronate gel approved for the treatment of osteoarthritis (OA) of the knee that does not respond to other conservative treatments. It is the first low-volume viscosupplement available in a single-injection formula.

Unlike other viscosupplement treatments, highly purified Gel-One Hyaluronate requires only 3mL for safe, effective and complete treatment with no reports of pseudosepsis (severe acute inflammatory responses) in the pre-market clinical study.

HCPCS (Healthcare Common Procedure Coding System) Codes	
Code	**Description**
J7326	Hyaluronan or derivative, Gel-One, for intra-articular injection, per dose

CPT (Current Procedural Terminology) Codes	
Code	**Description**
20610	Arthrocentesis, aspiration and/or injection, major joint or bursa (eg, shoulder, hip, knee, subacromial bursa); without ultrasound guidance
20611	Arthrocentesis, aspiration and/or injection, major joint or bursa (eg, shoulder, hip, knee, subacromial bursa); with ultrasound guidance, with permanent recording and reporting

CPT and HCPCS Modifiers	
Modifier	**Description**
LT	Left side (used to identify procedures performed on the left side of the body)
RT	Right side (used to identify procedures performed on the right side of the body)
50	Bilateral Procedure
59	Distinct Procedural Service (indicates that a procedure or service was distinct or independent from other non-E/M services performed on the same day)

Sample ICD-10-CM Diagnosis Codes	
Code	**Description**
M17.0	Bilateral primary osteoarthritis of knee
M17.10	Unilateral primary osteoarthritis, unspecified knee
M17.11	Unilateral primary osteoarthritis, right knee
M17.12	Unilateral primary osteoarthritis, left knee
M17.2	Bilateral post-traumatic osteoarthritis of knee
M17.30	Unilateral post-traumatic osteoarthritis, unspecified knee
M17.31	Unilateral post-traumatic osteoarthritis, right knee
M17.32	Unilateral post-traumatic osteoarthritis, left knee
M17.4	Other bilateral secondary osteoarthritis of knee
M17.5	Other unilateral secondary osteoarthritis of knee
M17.9	Osteoarthritis of the knee, unspecified

Note: Code assignment is based on the physician's documentation of the patient's condition. Codes listed are for illustrative purposes only.

NDC (National Drug Code)	
Code	**Description**
50016-0957-11	Gel-One Hyaluronate 3.0 ml (Effective 8/1/2020)
87541-0300-91	Gel-One Hyaluronate 3.0 ml

Coding and Billing for Gel-One Cross-Linked Hyaluronate

- Prior authorization/pre-determination is suggested prior to administration of Gel-One Cross-Linked Hyaluronate. The payer will want to review the product indications, dosage, route of administration and medical necessity.
- It is recommended providers bill for Gel-One showing both the J7326 HCPCS code and the NDC as reflected on the sample CMS-1500 claim form below. The following qualifiers are to be used when entering supplemental information for the billing of Gel-One.

  N4 National Drug Codes (NDC)

  ML Milliliter

  To enter supplemental information, begin at 24A on the CMS-1500 claim form by entering the qualifier and then the information. Do not enter a space between the qualifier and the number/code/information. Do not enter hyphens or spaces within the number/code. Add the supplemental information in the following order: qualifier, NDC code, one space, unit/basis of measurement qualifier, quantity. The number of digits for the quantity is limited to eight digits before the decimal and three digits after the decimal. If entering a whole number, do not use a decimal. Do not use commas.

Sample CMS-1500 Claim Form

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind. 0

A. M17.XX B. C. D.

E. F. G. H.

I. J. K. L.

22. RESUBMISSION CODE ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER XXXXXXXXXX

	24. A. DATE(S) OF SERVICE From MM	DD	YY	To MM	DD	YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
1	XX	XX	XX	XX	XX	XX	11		20610	LT	A	XXX	XX	1		NPI XXXXXXXXXX
2	N450016095711 ML3															
	XX	XX	XX	XX	XX	XX	11		J7326	LT	A	XXX	XX	1		NPI XXXXXXXXXX
3																NPI

SUPPLIER INFORMATION

Field 21: Enter the ICD-10-CM diagnosis code(s)
Field 23: Enter the payer prior authorization number received during the benefit investigation
Field 24A: Enter the product supplemental information (qualifier, NDC, measurement qualifier, quantity) along with the date of service
Field 24D: Enter the CPT/HCPCS code(s) for the services/products provided and any appropriate modifiers
Field 24E: Enter the diagnosis code reference letter (pointer) from field 21 to relate the date of service and the procedures performed to the primary diagnosis.
Field 24F: Enter the charge amount for each listed service.
Field 24G: Enter the number of days or units.

- The payment allowance limits for drugs and biologicals that are not included in the ASP Medicare Part B Drug Pricing File or Not Otherwise Classified (NOC) Pricing File, other than new drugs that are produced or distributed under a new drug application (or other application) approved by the Food and Drug Administration, are based on the published Wholesale Acquisition Cost (WAC) or invoice pricing, except under OPPS where the payment allowance limit is 95 percent of the published AWP. In determining the payment limit based on WAC, the contractors follow the methodology specified in Publication 100-04, Chapter 17, Drugs and Biologicals, for calculating the AWP, but substitute WAC for AWP. The payment limit is 106 percent of the lesser of the lowest-priced brand or median generic WAC.

  MACs shall develop payment allowance limits for covered drugs when CMS does not supply the payment allowance limit on the ASP drug pricing file. At the contractors' discretion, contractors may contact CMS to obtain payment limits for drugs not included in the quarterly ASP or NOC files or otherwise made available by CMS on the CMS Web site. If the payment limit is available from CMS, contractors will substitute CMS-provided payment limits for pricing based on WAC or invoice pricing. CMS will provide the payment limits either directly to the requesting contractor or via posting an MS Excel file on the CMS Web site.

  Source: Medicare Claims Processing Manual, Chapter 17 – Drugs and Biologicals, 20.1.3 – Exceptions to Average Sales Price (ASP) Payment Methodology

- The Wholesale Acquisition Cost (WAC) of Gel-One Cross-Linked Hyaluronate is published and available. Providers should be able to direct Medicare Administrative Contractors (MACs) to the published WAC before having to manually submit invoice documentation.

Hospital Outpatient and Ambulatory Surgical Center (ASC)				
Code	**Description**	**Ambulatory Payment Classification**	**OPPS Status Indicator**	**ASC Payment Indicator**
20610	Arthrocentesis, aspiration and/or injection, major joint or bursa (eg, shoulder, hip, knee, subacromial bursa); without ultrasound guidance	5441	T	P3
20611	Arthrocentesis, aspiration and/or injection, major joint or bursa (eg, shoulder, hip, knee, subacromial bursa); with ultrasound guidance, with permanent recording and reporting	5441	T	P3
J7326	Hyaluronan or derivative, Gel-One, for intra-articular injection, per dose	1417	K	K2

OPPS - Medicare's Outpatient Prospective Payment System.
APC: 1417 – Gel-One; 5441 - Level 1 Nerve Injections
Status Indicators: K - Nonpass-Through Drugs and Nonimplantable Biologicals, Including Therapeutic Radiopharmaceuticals. Paid under OPPS; separate APC payment. T – Multiple procedure reduction applies.
Payment Indicators: K2 - Drugs and biologicals paid separately when provided integral to a surgical procedure on ASC list; payment based on OPPS rate. P3 – Payment based on Medicare's Physician Fee Schedule (MPFS) non-facility Practice Expense (PE) Relative Value Units (RVUs).

Medicare Guidance for Injection Services

Where the sole purpose of an office visit was for the patient to receive an injection, payment may be made only for the injection service (if it is covered). Conversely, injection services included in the Medicare Physician Fee Schedule (MPFS) are not paid for separately if the physician is paid for any other physician fee schedule service furnished at the same time. Payment may be made for those injection services only if no other physician fee schedule service is being paid. All injection claims must include the specific name of the drug and dosage. Identification of the drug enables payment for the services.

Source: Medicare Claims Processing Manual, Chapter 17 – Drugs and Biologicals, 20.5.7 – Injection Services

For further assistance with reimbursement questions, contact the Zimmer Biomet Reimbursement Hotline at 866-946-0444 or reimbursement@zimmerbiomet.com, or visit our reimbursement web site at www.zimmerbiomet.com/reimbursement.

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