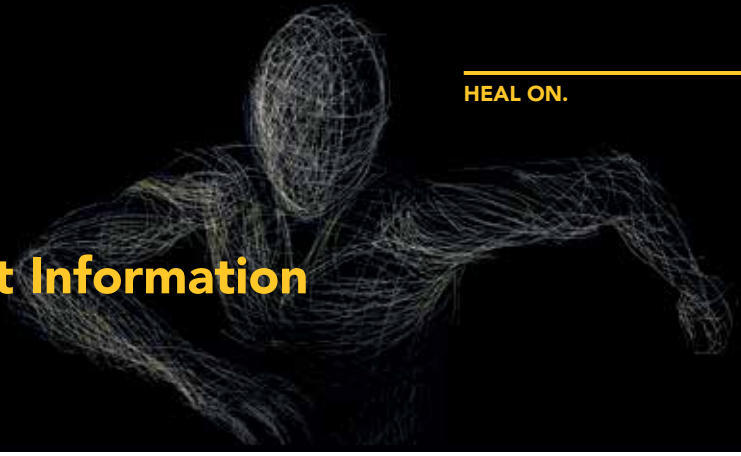


## Medicare Reimbursement Information

### Physician



Medicare nationally covers The Aurix System™ under the Coverage with Evidence Development (CED) framework. Aurix™ is covered by CMS for the purpose of collecting data to demonstrate health outcomes specific to Medicare patients. CMS has approved data collection protocols and thus covers Aurix™ treatment for<sup>1</sup>:

- Diabetic foot ulcers
- Venous leg ulcers
- Pressure ulcers

Please contact your Account Executive for details regarding these protocols.

Coverage under private insurance and Medicaid is currently determined on a case-by-case basis. Please contact [info@nuot.com](mailto:info@nuot.com) or [1.866.298.6633](tel:1.866.298.6633) for information on submitting a claim for Aurix™ to one of the following payers.

1 U.S. Food and Drug Administration. 510(k) Summary. Autogel® System. Sept. 7, 2007. Last accessed June 23, 2014. <<http://www.fda.gov/downloads/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/SubstantiallyEquivalent510kDeviceInformation/UCM073104.pdf>> PDF file.

The information in this document is gathered from public sources and is provided here for illustrative purposes only. This information cannot cover all situations or all third-party payer rules or policies, nor can use of this information guarantee coverage or payment. This document makes no other representations or warranties as to selecting codes for procedures or compliance with any other billing protocols or prerequisites. As with all claims, individual providers and suppliers are responsible for exercising independent clinical judgment in selecting the codes that most accurately reflect a patient's condition and the procedures performed. Laws, regulations, and policies concerning coding and payment are complex and subject to change.

You should refer to current, complete and authoritative publications such as Medicare transmittals, AMA CPT lists, and third-party insurer policies as the basis for selecting codes that describe care rendered to an individual patient, and you may wish to contact individual payers as needed.



## Coding and Payment for the Aurix System™

### Physician Office Setting (Place of Service (POS) 11)

Unlike skin substitute or other procedures where there are separate procedure (CPT) and product (HCPCS “Q”) codes, coding for Aurix is simplified with one HCPCS code, G0460 (G-zero-four-six-zero). The use of this code allows Medicare Administrative Contractors (MACs) to identify the use of Aurix. Below are the codes and modifiers that may be used during a typical patient encounter where Aurix would be used.

HCPCS Codes/Modifiers	Description	2014 Medicare Average National Payment
G0460/-Q0 (zero)	PRP Gel procedure/Modifier indicates the code is payable for the CED protocol	Contractor-determined*
HCPCS Codes/Modifiers	Description	2014 Medicare Average National Payment
11042	Debridement, subcutaneous tissue, first 20 cm <sup>2</sup> ; each add'l 20 cm <sup>2</sup>	\$120.10
11043	Debridement, muscle and/or fascia, first 20 cm <sup>2</sup>	\$234.42
11044	Debridement, bone, first 20 cm <sup>2</sup>	\$322.41
97597	Debridement, open wound, including topical applications, first 20 cm <sup>2</sup>	\$77.02

As with any claim, you must list the diagnosis code(s) to which the procedure or item codes match. In the table below are the diagnosis codes that will indicate that the patient is enrolled in the CED protocol.

ICD-9-CM Diagnosis Code	Description
Code for etiology of wound	Primary Diagnosis (MAC will list)
V70.7	Secondary Diagnosis (participant in CED protocols)

Effective January 1, 2014, CMS requires that for any covered services provided in a clinical trial, which includes the Aurix CED protocols, the 8-digit clinical trial be reported on the claim. This value will be reported in Box 19 of the CMS-1500 form.

Aurix Protocol No.	Description	Clinical Trial No. ( <a href="http://www.Clinicaltrials.gov">www.Clinicaltrials.gov</a> )
CM001	Diabetic Foot Ulcer Randomized Controlled Trial	01816672
CM002	Diabetic Foot Ulcer Cohort Trial	01816633
CM003	Venous Leg Ulcer Cohort Trial	01817543
CM004	Pressure Ulcer Cohort Trial	01819142

# Coding and Payment for the Aurix System™

## Hospital Outpatient Department Setting (POS 22)

Beginning January 1, 2014, Medicare has placed G0460 (G-zero-four-six-zero), the code for the Aurix process, in the Ambulatory Payment Classification (APC) code 0327, which has a national average payment of \$409. Unlike procedures involving skin substitutes, hospitals need only record G0460 (and the modifiers in the table) on the claim for it to be accepted for payment. The CPT codes listed below G0460 may be part of the clinical scenario during the full patient encounter, and could be subject to multiple procedure payment reduction rules.

For documentation from CMS that allows Medicare Administrative Contractors (MACs) to accept claims with G0460, please see the MLN Matters Number MM8213, which can be downloaded from the CMS website, or is available from your Nuo Therapeutics Account Executive.

HCPCS Codes/Modifiers	Description	2014 Medicare Average National Payment
G0460/-Q0 (zero)	PRP gel procedure/Modifier indicates the code is payable for the CED protocol	Contractor-determined*
CPT Codes/Modifiers	Description	2014 Medicare Average National Payment
11042	Debridement, subcutaneous tissue, first 20 cm <sup>2</sup> ; each add'l 20 cm <sup>2</sup>	\$63.05
11043	Debridement, muscle and/or fascia, first 20 cm <sup>2</sup>	\$161.20
11044	Debridement, bone, first 20 cm <sup>2</sup>	\$240.37
97597	Debridement, open wound, including topical applications, first 20 cm <sup>2</sup>	\$24.72

\*MACs will determine the payment rate for this code, based on the charges you submit. The detachable worksheet on the next page will help you determine the charges to submit to the MAC.

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# Cost Factor Checklist for Physician Offices

## HCPCS Code G0460

The Centers for Medicare and Medicaid Services (CMS) has instructed Medicare Administrative Contractors (MACs) to determine the payment amount for HCPCS Code G0460 based on the charges received from physician offices. MACs generally consider documentation provided by practitioners as the basis for the submitted charges. This checklist, along with any other documentation, such as invoices from manufacturers and suppliers, may be used as part of such documentation. Please note that the item listed and the amounts you list on this document are no guarantee of payment from Medicare, and the MACs have discretion in setting payment amounts.

*Code Description: Autologous platelet rich plasma for chronic wounds/ulcers, including phlebotomy, centrifugation, and all other preparatory procedures, administration and dressings, per treatment.*

Item	Source of Documentation	Estimated Charge
Aurix System: kits and centrifuge	Invoice	
Phlebotomy	In-house resources used or invoice from phlebotomist	
Preparation of patient for treatment, not including debridement of wound	In-house resources used, including time spent by all relevant staff members	
Administration of Aurix and dressings	In-house resources used, including time spent by all relevant staff members	
Supplies not accounted for above	In-house resources used, invoices if applicable	
Patient QOL survey and counseling	In-house resources used, including time spent by all relevant staff members	
Total resources expended:		