

**Appropriate Medicare Payment for Newly Approved
Blood Component Products Billed on an Interim Basis
With “Not Otherwise Classified” Code**

Advisory Panel on Hospital Outpatient Payment | August 23, 2021

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Presenters:

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Jessica Hanover, PhD is an employee of Cerus Corporation, which has developed five FDA-approved blood component products, and is currently developing additional new blood component products

Affected HCPCS Code and APC

- **HCPCS code P9099** (Blood component or product, not otherwise classified)
- HCPCS P9099 is currently assigned **APC 9537** (status indicator “R”)

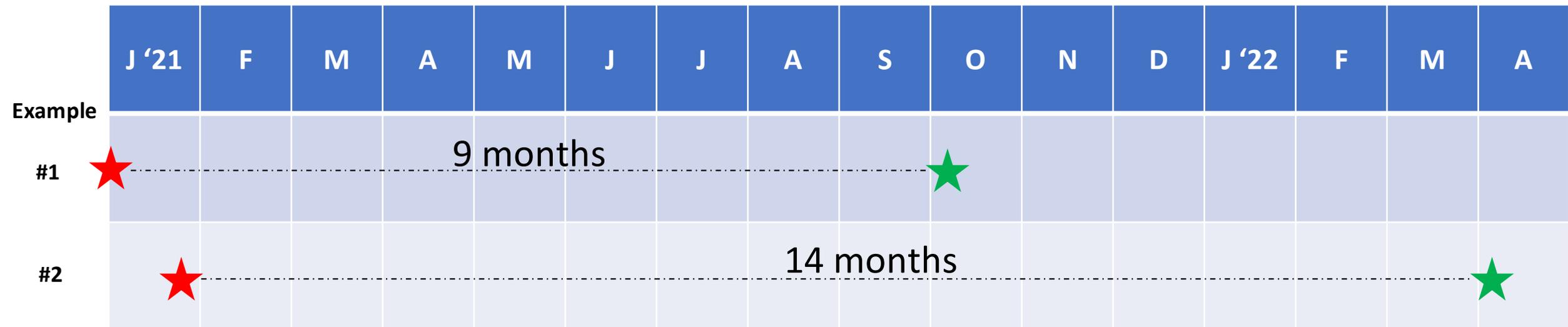
Any new FDA-approved blood product(s) temporarily billed with HCPCS P9099 in CY 2021 is assigned to APC 9537 with a Medicare OPPS payment rate of **\$7.99 per unit**, assigned on the basis of the lowest-cost blood product in the blood product “service category”

A Number of New Types of Blood Component Products are Currently in Development

Investigational Product	Manufacturer	Current Development Status
Freeze dried plasma	Teleflex	Submission requesting FDA marketing approval in February 2021.
Amustaline/glutathione-treated, pathogen reduced red blood cells	Cerus	Currently in Phase 3 clinical testing
Freeze dried, heat-treated platelets (Thrombosomes [®])	CellPhire	Currently in Phase 2 clinical testing
Spray dried plasma	Velico Medical	Pre-clinical development
Hemanext ONE-processed red blood cells	Hemanext	Completed Phase 2 clinical testing

Description of the Issue

- A number of innovative new blood products are expected to be approved and introduced in CY 2021 and over the next several years
- In response to a request by providers and stakeholders, **CMS established HCPCS P9099** (Blood component or product, NOC) **for use by hospitals to bill for any new blood product prior to establishment of a permanent HCPCS billing code**
- A lag period of up to one year or longer can occur between **FDA approval** and the **assignment of a permanent HCPCS billing code** for a new blood product:



Description of the Issue (continued)

- Unlike sole-sourced new drugs/biologicals identified by their NCD code and billed with HCPCS C9399, new blood products are supplied by numerous blood center “manufacturers.”
- **No published price list or compendium exists that A/B MACs can reference to assign a payment rate to new blood product(s) billed with HCPCS P9099.**
- CMS has variously proposed or implemented several payment policies for HCPCS P9099; **none of these payment policies meaningfully compensates hospitals for actual realized costs of new blood products.**

Proposed or Implemented CMS Payment Policies for HCPCS P9099

Do Not Compensate Hospitals for Actual Blood Product Costs, Presenting a Financial Barrier to Patient Access

Status Indicator	Proposed or implemented policy	Problem(s)	Patient Access Barrier?
“E2”	Not paid by Medicare when submitted on outpatient claims	No payment for new blood component products that range widely in cost from <\$100 up to >\$800/unit	Yes
“N”	Paid under OPPS; payment is packaged into payment for other services. Therefore, no separate payment	“Packaging” with associated transfusion service effectively yields no payment for new blood products billed with P9099	Yes
“R”	Paid under OPPS; separate APC payment equivalent to payment rate for lowest cost blood product.	An \$8 payment rate premised on assertion that blood products comprise a single “service category”	Yes

Description of the Issue (continued)

For CY 2022, CMS has again proposed to make any new blood product coded with HCPCS P9099 separately payable at a rate equal to the lowest paid blood product, which is **HCPCS P9043 (Plasma protein fraction, 5%, 50 mL) with a proposed 2022 payment rate of \$8.21.**

In its response to commenters, **CMS raised concerns that paying unclassified blood products using reasonable cost “could discourage manufacturers of new blood products from seeking individual HCPCS codes for their products.”**

CMS added that **“we understand that...the lowest payment rate for a separately payable blood product in the OPPS does not provide adequate payment for new, unclassified blood products. However, our goal is to limit the time it is necessary for providers to report HCPCS code P9099 until...a new individual HCPCS code is established for the product.”**

We disagree with CMS’ characterization of blood products – which are extraordinarily diverse in composition, function and cost – as a single “category of service,” as well as the policy decision that follows to pay for any new blood product on the basis of the lowest-paying APC/blood product in the “category”

	RED BLOOD CELLS	PLATELETS	PLASMA	COLLOIDS
				
Function(s)	Oxygen delivery to organs and tissues	Control and prevention of bleeding	Delivery of critical coagulation factors and plasma volume	Blood volume expansion
Medicare Payment Rate Range	\$138 - \$437	\$71 - \$805	\$66 - \$123	\$8 - \$160

Examples of HCPCS-Coded Blood Component Products; 2021 Rates

P Code	Product Description	2021 Rate
P9016	RBCs, leukocytes reduced	\$188.51
P9040	RBCs, leukoreduced (LR), irradiated	\$260.55
P9022	Washed red blood cells	\$379.86
P9035	Platelets, pheresis, leukoreduced	\$486.80
P9073	Platelets, pheresis, path reduced	\$583.87
P9037	Platelets, pher, hla-m, LR	\$617.83
P9021	Platelets, pheresis, LR, irradiated	\$805.18

P Code	Product Description	2021 Rate
P9033	Platelets, LR, irradiated	\$213.19
P9059	Plasma, frz between 8-24 hr	\$71.15
P9032	Plasma, 1 donor, frz w/in 1 hr	\$82.66
P9012	Cryoprecipitate	\$79.85
P9043	Plasma protein frac 5%, 50 ml	\$7.99
P9048	Plasma protein frac 5% 250 ml	\$169.31
P9045	Albumin 5%, 250 ml	\$52.45

We find no basis for CMS' concern that payment for new blood products at reasonable cost, based on supplier invoice, could discourage manufacturers from seeking permanent HCPCS codes:

1. MAC payment for a new blood product on the basis of the blood supplier's invoiced amount provides no financial incentive for hospitals that in turn might encourage manufacturers to delay applying for a permanent HCPCS code
2. To the contrary, manual preparation of HCPCS P9099 claims accompanied by blood supplier invoice involves significant uncompensated hospital billing staff time costs, creating a significant incentive for the blood product manufacturer to expeditiously apply for a permanent HCPCS code

Recommendations and Rationale for Change

- **We recommend that the HOP Panel request that CMS assign the “F” status indicator to HCPCS P9099**, to authorize A/B MACs to compensate hospitals for new blood products temporarily billed with HCPCS P9099 on the basis of reasonable cost
- We further recommend that CMS stipulate, as it does for corneal tissue acquisition services, that **the blood supplier’s invoice be appended to HCPCS P9099 claims and comprise the basis for reasonable cost payment**
 - This payment policy will ensure that hospitals are adequately compensated for the costs of innovative new blood products, and that patients are ensured access to these products during the interim period prior to establishment of permanent HCPCS codes.
 - As no financial incentive exists for hospitals to bill new blood products with HCPCS P9099 with Medicare payment based on invoiced acquisition cost, there is no basis for a concern that manufacturers will have an incentive to delay or avoid applying for permanent HCPCS codes for their newly FDA-licensed blood products

Potential Consequences of Not Making the Requested Change

- Inability of physicians and patients to access newly FDA-licensed blood products with the potential to facilitate improved health outcomes, in the event that CMS finalizes its proposed policy to assign a payment rate of <\$10 for HCPCS P9099 on the basis of the lowest-cost OPPS blood product
- An incentive for miscoding new blood products with an existing HCPCS code, in an attempt to secure compensation for the hospital's incurred product costs
- Suppression of new blood product innovation, as prospective developers and blood suppliers are dissuaded by expected resistance from hospitals unwilling to accept a token Medicare payment relative to actual product cost