Association for the Advancement of Blood & Biotherapies

Billing for LVDS-tested and Pathogen-reduced Platelets

In a final guidance document published in September 2019 (updated in December 2020), the U.S. Food and Drug Administration (FDA) recommends large volume delayed sampling (LVDS) and pathogen reduction as single-step strategies for mitigating the risk of bacterial contamination of platelets. (Single-step strategies require no other steps prior to release of platelet units for transfusion; all work is performed by the blood center, which simplifies the process for the hospital.) The implementation deadline for the guidance was October 1, 2021.[1]

To ensure that their platelet supplies are in compliance with the FDA guidance, many blood centers have implemented LVDS (which is relatively new to the U.S.) or increased their utilization of pathogen reduction. These developments, along with an important Centers for Medicare and Medicaid Services (CMS) coding update, have prompted questions from hospitals about billing for LVDS-tested platelets and pathogen-reduced platelets. Both of these topics are covered in this fact sheet.

Billing for LVDS-Tested Platelets

In August 2021, CMS published a final Healthcare Common Procedure Coding System (HCPCS) coding decision stating that LVDS-tested platelets could be reported using a combination of the applicable platelet P-code plus HCPCS code P9100 (Pathogen(s) test for platelets).[2] This decision means that hospitals should use P9100 to bill for the additional fee associated with LVDS testing in the outpatient setting, as shown in the following examples:

The billing information in this fact sheet applies only to the hospital **outpatient setting.** CPT and HCPCS codes are generally not used on hospital inpatient claims.

LVDS-tested leukocyte-reduced apheresis platelets:

P9035 + **P9100**

Platelets, pheresis, leukoreduced, each unit | *Pathogen(s) test for platelets*

LVDS-tested leukocyte-reduced whole blood-derived platelets:

P9031 + **P9100**

Platelets, leukoreduced, each unit | *Pathogen(s) test for platelets*

Important Notes Regarding HCPCS Code P9100

- HCPCS code P9100 is a testing code and not a product code.
- Like other laboratory testing codes, P9100 should be billed in addition to the appropriate blood product P-code when units are transfused.
- If LVDS-tested platelets are ordered for a specific patient but are not transfused, hospitals would not be able to bill the P-code for the platelet units or the transfusion Current Procedural Terminology (CPT) code, but could still bill P9100 for the LVDS testing.
- As with other types of laboratory tests performed on blood units, it is recommended that hospitals report P9100 with revenue code series 030X or 031X.
- Prior to CMS's August 2021 coding decision, the only type of pathogen testing described by P9100 was rapid bacterial testing of platelets. P9100 can still be used to report rapid bacterial testing (which is part of a two-step strategy recommended in the FDA platelet guidance), but its use has expanded to also include LVDS testing.[3]

Billing for Pathogen-Reduced Platelets

The following HCPCS P-code specifically describes pathogen-reduced platelets:

- P9073 – Platelets, pheresis, pathogen reduced, each unit

Unlike LVDS testing, pathogen reduction is included in the product code (P9073) and cannot be billed separately. If pathogen-reduced units are ordered for a specific patient but are not transfused, then no code would be billed.

Note: It would not be appropriate to use HCPCS code P9100 for pathogen reduction. P9100 should only be used to report LVDS testing and rapid bacterial testing of platelets (as described above).

Key Takeaways

- Use HCPCS code **P9100** in addition to the applicable platelet P-code to bill for LVDS testing.
  - P9100 can also be used to report rapid bacterial testing of platelets.
- Use HCPCS code **P9073** to bill for pathogen-reduced platelets.
  - Pathogen reduction is included in P9073 and cannot be billed separately.

Additional Resources

The FDA final guidance document on bacterial risk mitigation for platelets is available at: fda.gov/media/123448/download.

AABB is providing this fact sheet as a supplement to its Billing Guide for Blood Products and Related Services, which has been newly updated for 2023. The AABB Billing Guide contains a wealth of information on reimbursement for blood products, transfusion procedures, and patient-specific laboratory services performed on blood units. To download the latest version of the Billing Guide, go to: aabb.org/BillingGuide.

References

1. U.S. Food and Drug Administration. Bacterial risk control strategies for blood collection establishments and transfusion services to enhance the safety and availability of platelets for transfusion: Guidance for Industry. September 2019. Updated December 2020. Silver Spring, MD: FDA. [Available at: https://www.fda.gov/media/123448/download (accessed October 5, 2023).]
2. Centers for Medicare and Medicaid Services. Healthcare Common Procedure Coding System (HCPCS) Application Summaries and Coding Decisions: First Biannual, 2021 HCPCS Coding Cycle. Updated 08/09/2021. Pages 20-23. Balitmore, MD: CMS. [Available at: https://www.cms.gov/files/document/2021-hcpcs-application-summary-bi-annual-1-2021-non-drug-and-non-biological-items-and-services.pdf (accessed October 5, 2023).]
3. Centers for Medicare and Medicaid Services. Calendar year 2022 OPPS final rule with comment period. November 16, 2021. Fed Regist 2021;86(218):63560. [Available at: https://www.govinfo.gov/content/pkg/FR-2021-11-16/pdf/2021-24011.pdf (accessed October 5, 2023).]