

## **Physician Self-referral Law**

### **Annual Update to the List of CPT/HCPCS Codes Effective January 1, 2023**

#### **I. Background**

Section 1877 of the Social Security Act (the Act), also known as the physician self-referral law: (1) Prohibits a physician from making referrals for certain designated health services payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship unless the requirements of an applicable exception are satisfied; and (2) prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third party payer) for any improperly referred designated health services. The physician self-referral regulations are found at 42 CFR Part 411 Subpart J. In § 411.351, we specify that the entire scope of four categories of designated health services is defined in a list of CPT/HCPCS codes (the Code List), which is updated annually to account for changes in the most recent CPT and HCPCS Level II publications. The categories defined and updated in this manner are:

- Clinical laboratory services.
- Physical therapy, occupational therapy, and outpatient speech-language pathology services.
- Radiology and certain other imaging services.
- Radiation therapy services and supplies.

The Code List also identifies those items and services that may qualify for either of the following two exceptions to the physician self-referral prohibitions:

- EPO and other dialysis-related drugs (§ 411.355(g)).
- Preventive screening tests, immunizations, and vaccines (§ 411.355(h)).

Beginning with the January 1, 2023 Code List, we will publish the Code List solely on the CMS website. (See the CY 2022 Physician Fee Schedule (PFS) final rule for further information (86 FR 65356 through 65357)).

The definition of “designated health services” at § 411.351 excludes services for which payment is made by Medicare as part of a composite rate (unless the services are specifically included in the statutory or regulatory lists of items and services that are designated health services and are themselves payable through a composite rate, such as home health and inpatient and outpatient hospital services). For example, effective January 1, 2011, EPO and dialysis-related drugs furnished in or by an ESRD facility (except drugs for which there are no injectable equivalents or other forms of administration), have been reimbursed under a composite rate known as the ESRD prospective payment system (ESRD PPS) (75 FR 49030). Accordingly, EPO and any dialysis-related drugs that are paid for under ESRD PPS are not designated health services and are not listed among the drugs that could qualify for the exception at § 411.355(g) for EPO and other dialysis-related drugs furnished by an ESRD facility. In contrast, ESRD-related oral-only drugs, which are drugs or biologicals with no injectable functional equivalents or other forms of administration other than an oral form, were scheduled to be paid under ESRD PPS beginning

January 1, 2014 (75 FR 49044). However, there have been several delays of the implementation of payment of these drugs under ESRD PPS. On December 19, 2014, section 204 of the Stephen Beck, Jr., Achieving a Better Life Experience Act of 2014 (ABLE) (Pub. L. 113–295) was enacted and delayed the inclusion of these oral-only drugs under the ESRD PPS until 2025. Until that time, such drugs furnished in or by an ESRD facility are not paid as part of a composite rate and, thus, are designated health services.

### COVID-19

The United States continues to respond to the outbreak of COVID–19 caused by the severe acute respiratory syndrome coronavirus 2 (SARS–CoV–2). Because the Federal Government is still purchasing the supply of COVID–19 vaccines, Medicare does not make payment for COVID–19 vaccines at this time, and COVID–19 vaccines do not fall within the definition of “designated health service” at § 411.351. However, should COVID–19 vaccines become payable by Medicare, unless the requirements of an applicable exception to the physician self-referral law are satisfied, the physician self-referral law’s prohibitions under section 1877(a)(1) of the Act and § 411.353(a) and (b) will apply to the referral and billing of COVID–19 vaccines.

For the Code List effective January 1, 2022, we added COVID–19 vaccines to the list of immunization and vaccine codes to which the exception at § 411.355(h) is applicable. We did so to ensure that the physician self-referral law will not impede the availability of COVID–19 vaccines for Medicare and other patients if they become payable by Medicare (85 FR 84955). For the same reason, we are including COVID-19 vaccines on the CY 2023 Code List. (See the CY 2022 PFS final rule for further information (85 FR 84954 through 85955)). Note that the inclusion of CPT code 90749 on the Code List is not intended and should not be considered to direct or approve the use of CPT code 90749 for the identification and billing of any COVID–19 vaccine.

Currently, monoclonal antibody products used to treat COVID–19 are covered and paid for under the COVID–19 vaccine benefit in section 1861(s)(10) of the Act. CMS makes a separate payment for the products (when not given to the provider or supplier for free by the government) and for the service to administer them. As “vaccines,” the products are designated health services for purposes of the physician self-referral law. Monoclonal antibody products covered and paid under the COVID–19 vaccine benefit in section 1861(s)(10) of the Act are included in the January 1, 2023 list of codes that are eligible for the exception at § 411.355(h) as “any future CPT or HCPCS code designated for a COVID–19 vaccine.”

## **II. Response to Comments on CY 2022 Code List**

We received no comments relating to the January 1, 2022 Code List.

## **III. Instructions for Submitting Comments on CY 2023 Code List.**

We will consider comments regarding the codes listed in the tables in section IV below. To submit a comment, go to [www.regulations.gov](http://www.regulations.gov) and enter the docket number “CMS-2022-0152” in the search field. Select the “Comment” button and follow the instructions. To be considered,

comments must be received on or before December 30, 2022. Comments will be made public, so submitters should not include any confidential or personal information. Please note that we will not consider any comment that advocates a substantive change to any of the designated health services defined in § 411.351.

#### **IV. Revisions Effective for CY 2023**

The updated Code List effective January 1, 2023, is available on our website at [https://www.cms.gov/medicare/fraud-and-abuse/physiciansselfreferral/list\\_of\\_codes](https://www.cms.gov/medicare/fraud-and-abuse/physiciansselfreferral/list_of_codes). Additions and deletions to the Code List conform it to the most recent publications of CPT and HCPCS Level II and to changes in Medicare coverage policy and payment status. In the charts below, we identify the additions and deletions, respectively, to the Code List that is effective January 1, 2023. The charts below also include the additions and deletions to the list of codes used to identify the items and services that may qualify for the exception in § 411.355(g) (regarding dialysis-related outpatient prescription drugs furnished in or by an ESRD facility) and in § 411.355(h) (regarding preventive screening tests, immunizations, and vaccines).

Finally, based on a review of the Code Lists from CY 2012 through CY 2022, we are making several corrections to the CY 2023 Code List. These changes are also included in the charts below and will become effective January 1, 2023.

- Removing “77063 Breast tomosynthesis bi” and “77067 Scr mammo bi incl cad” from the Code List. These codes do not meet the requirements of section 1861(s)(4) of the Act or our regulations at § 411.351.
- Removing “93875 Extracranial study” from the Code List. This code was listed in the CY 2012 Physician Fee Schedule as a code that would be deleted, but was inadvertently retained on the Code List.
- Removing “G0476 Hpv combo assay ca screen” from the preventive screening tests and vaccines category because this code does not have frequency limits, which is a requirement of the exception at § 411.355(h). This code will remain in the clinical laboratory services category.
- Removing “C9734 U/s trtmt, not leiomyomata” from the radiation therapy services and supplies category. This code does not meet the definition of radiation therapy services in our regulations at § 411.351. This code will remain in the radiology and certain other imaging services category.

Additions to the Physician Self-Referral List of CPT<sup>1</sup>/HCPCS Codes

| <b>CLINICAL LABORATORY SERVICES</b>  |                              |
|--|------------------------------|
| <b>(INCLUDE codes for all clinical laboratory services in the 80000 series)</b>                                    |                              |
| <b>BLOOD COMPONENT COLLECTION SERVICES IN THE 80000 SERIES THAT ARE EXCLUDED FROM CLINICAL LABORATORY SERVICES</b> |                              |
| {No Additions}   |                              |
| <b>OTHER CODES NOT IN 80000 SERIES INCLUDED IN CLINICAL LABORATORY SERVICES</b>                                    |                              |
| 0287U  | Onc thyr dna&mrna 112 genes  |
| 0288U  | Onc lung mrna quan pcr 11&3  |
| 0305U  | Hem rbc fnclty&dfrm shr strs |
| 0306U  | Onc mrd nxt-gnrj alys 1st    |
| 0307U  | Onc mrd nxt-gnrj alys sbsq   |
| 0313U  | Onc pncrs dna&mrna seq 74    |
| 0314U  | Onc cutan mlnma mrna 35 gene |
| 0315U  | Onc cutan sq cll ca mrna 40  |
| 0317U  | Onc lung ca 4-prb fish assay |
| 0318U  | Ped whl gen mthyltn alys 50+ |
| 0332U  | Onc pan tum gen prflg 8 dna  |
| 0334U  | Onc sld orgn tgasa dna 84/+  |
| 0335U  | Rare ds whl gen seq feta     |
| 0336U  | Rare ds whl gen seq bld/slv  |
| <b>PHYSICAL THERAPY, OCCUPATIONAL THERAPY, AND OUTPATIENT SPEECH-LANGUAGE PATHOLOGY SERVICES</b>                   |                              |
| {No Additions}   |                              |
| <b>RADIOLOGY AND CERTAIN OTHER IMAGING SERVICES</b>  |                              |
| 0721T  | Quan ct tiss charac w/o ct   |
| 0722T  | Quan ct tiss charac w/ct     |
| 0723T  | Qmrcp w/o dx mri sm anat ses |
| 0724T  | Qmrcp w/dx mri same anatomy  |
| A9596  | Gallium illuccix 1 millicure |
| A9601  | Flortaucipir inj 1 millicuri |
| A9602  | Fluorodopa f-18 diag per mci |
| A9800  | Gallium locametz 1 millicuri |
| 76883  | Us nrv&acc strux 1xtr compre |
| <b>RADIATION THERAPY SERVICES AND SUPPLIES</b>   |                              |
| A9607  | Lutetium lu 177 vipivotide   |

<sup>1</sup> CPT codes and descriptions only are copyright 2023 AMA. All rights are reserved and applicable FARS/DFARS clauses apply.

| <b>DRUGS USED BY PATIENTS UNDERGOING DIALYSIS</b> |                              |
|---|------------------------------|
| {No Additions}                                    |                              |
| <b>PREVENTIVE SCREENING TESTS AND VACCINES</b>    |                              |
| Q0220   | Tixagev and cilgav, 300mg    |
| Q0221   | Tixagev and cilgav, 600mg    |
| Q0222   | Bebtelovimab 175 mg          |
| 91308   | Sarscov2 vac 3 mcg trs-sucr  |
| 91309   | Sarscov2 vac 50mcg/0.5ml im  |
| 91310   | Sarscov2 vac 5mcg/0.5ml as03 |
| 91311   | Sarscov2 vac 25mcg/0.25ml im |
| 91312   | Sarscov2 vac bvl 30mcg/0.3ml |
| 91313   | Sarscov2 vac bvl 50mcg/0.5ml |
| 91314   | Sarscov2 vac bvl 25mcg/.25ml |
| 91315   | Sarscov2 vac bvl 10mcg/0.2ml |

Deletions from the Physician Self-Referral List of CPT<sup>2</sup>/HCPCS Codes

| <b>CLINICAL LABORATORY SERVICES</b>  |                             |
|--|-----------------------------|
| <b>BLOOD COMPONENT COLLECTION SERVICES IN THE 80000 SERIES THAT ARE EXCLUDED FROM CLINICAL LABORATORY SERVICES</b> |                             |
| {No Deletions}   |                             |
| <b>OTHER CODES NOT IN 80000 SERIES INCLUDED IN CLINICAL LABORATORY SERVICES</b>                                    |                             |
| 0056U  | Hem aml dna gene reargmt    |
| 0208U  | Onc mtc mrna xprsn alys 108 |
| <b>PHYSICAL THERAPY, OCCUPATIONAL THERAPY, AND OUTPATIENT SPEECH-LANGUAGE PATHOLOGY SERVICES</b>                   |                             |
| {No Deletions}   |                             |
| <b>RADIOLOGY AND CERTAIN OTHER IMAGING SERVICES</b>  |                             |
| 93875  | Extracranial study          |
| 77063  | Breast tomosynthesis bi     |
| 77067  | Scr mammo bi incl cad       |
| <b>RADIATION THERAPY SERVICES AND SUPPLIES</b>   |                             |
| C9734  | U/s trtmt, not leiomyomata  |

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| <b>DRUGS USED BY PATIENTS UNDERGOING DIALYSIS</b> |  |
|---|--|
|---|--|

|                |  |
|----------------|--|
| {No Deletions} |  |
|----------------|--|

| <b>PREVENTIVE SCREENING TESTS AND VACCINES</b> |  |
|--|--|
|--|--|

|       |                           |
|-------|---------------------------|
| G0476 | Hpv combo assay ca screen |
|-------|---------------------------|

|       |                         |
|-------|-------------------------|
| 77063 | Breast tomosynthesis bi |
|-------|-------------------------|

|       |                       |
|-------|-----------------------|
| 77067 | Scr mammo bi incl cad |
|-------|-----------------------|