DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

CENTER FOR MEDICARE

TO: All Part D Plan Sponsors

FROM: Amy Larrick Chavez-Valdez, Director
Medicare Drug Benefit and C & D Data Group

SUBJECT: Sensipar® (cinacalcet) Furnished for the Treatment of ESRD Moving from Part D to ESRD PPS, Effective January 1, 2018

DATE: August 18, 2017

The purpose of this memorandum is to provide an update to Part D sponsors regarding drugs and biologicals used for the treatment of End Stage Renal Disease (ESRD), specifically Sensipar® (cinacalcet).

Currently, drugs used for the provision of renal dialysis services are defined in 42 CFR 413.234(a) *as a drug or biological with no injectable equivalent or other form of administration other than an oral form.* These drugs are excluded from the ESRD Prospective Payment System (PPS) bundled payment, and consequently paid through Part D. Presently, Sensipar (cinacalcet) meets the definition under 42 CFR 413.234(a) and is therefore paid under the Part D benefit.

Recently, however, an injectable drug Parsabiv® (etelcalcetide) that falls within the bone and mineral metabolism functional category has been approved for renal dialysis services by the United States Food and Drug Administration (FDA). Therefore, **beginning January 1, 2018**, the injectable drug Parsabiv® (etelcalcetide) will be included in the ESRD PPS. With the inclusion of Parsabiv® in the ESRD PPS, Sensipar® (cinacalcet) will also now be included in the ESRD PPS and therefore no longer payable under the Part D benefit when used for the provision of renal dialysis services.[1] As a result, Part D sponsors will have the opportunity to modify their CY 2018 formularies to add a Part B versus Part D prior authorization (PA) to cinacalcet. CMS will provide Part D sponsors with further guidance on submitting this change.

[1] In 42 CFR 413.234 (d), an oral-only drug is no longer considered oral-only if an injectable or other form of administration of the oral-only drug is approved by the Food and Drug Administration.