

**NOTICE TO 340B COVERED ENTITIES REGARDING
REPLACEMENT NDCS FOR ENBREL®**

Background:

Enbrel® (etanercept) containers (syringes, auto-injectors and cartridges) have always been filled with product volumes of either 0.98 mL or 0.51 mL, with strengths of either 50 mg/mL or 25 mg/0.50 mL, respectively (depending on the NDC). Historically, the Enbrel® label has reflected these *actual* product volumes of 0.98 mL or 0.51 mL.

In June 2018, at the request of the U.S. Food and Drug Administration, Amgen revised the Enbrel® label to reflect *rounded* product fill volumes of 1.00 mL and 0.50 mL, with strengths of 50 mg/1.00 mL or 25 mg/0.50 mL, respectively (again depending on the NDC). Importantly, this label change does not represent a change in any dosage form, strength or product composition of any Enbrel® NDC, and instead reflects a change in the *labeled* fill volume only.

Amgen assigned new NDC-9s to each Enbrel® product that then could align with the revised, rounded labeled fill volumes of 1.0 and .50 mL. Importantly, Amgen did not change the WAC for any of the NDCs impacted.

New NDCs and 340B Purchasing, In General:

Beginning in August 2019, Amgen began selling Enbrel® bearing the new NDCs for four of the existing Enbrel® products and also began phasing out the corresponding old NDCs. Despite the NDC update, there is **no change to the existing product (drug, dose, formulation, or volume) or price, as represented by the corresponding old and new NDCs.**

The table below reflects the old and new NDCs for Enbrel®. Please note that each new NDC is a *replacement* for an old NDC, and thus each pair of old/new NDCs is treated as if it were the *same* NDC for purposes of pricing and purchasing from Amgen through the 340B program.

| Old NDC | Description | New NDC |
|---------------|-------------------------|---------------|
| 58406-0456-04 | 50 mg Enbrel Mini® | 58406-0044-04 |
| 58406-0445-04 | 50 mg Enbrel SureClick® | 58406-0032-04 |
| 58406-0455-04 | 25 mg Enbrel® PFS | 58406-0010-04 |
| 58406-0435-04 | 50 mg Enbrel® PFS | 58406-0021-04 |

340B Inventory Replenishment:

Because the new NDCs are, in fact, the same product (drug, dose, formulation, or volume) with the same price as the corresponding old NDCs, Amgen believes that a covered entity utilizing a 340B inventory replenishment model may count accumulations of the Old NDC's toward replenishment of equal quantities of the corresponding New NDC (see above table).

Any questions regarding this matter can be directed to 340Brelations@amgen.com.