

Qwo[™] (collagenase clostridium histolyticum-aaes) – New drug approval

- On July 6, 2020, [Endo announced](#) the FDA approval of [Qwo \(collagenase clostridium histolyticum-aaes\)](#), for the treatment of moderate to severe cellulite in the buttocks of adult women.
- Qwo is the first FDA-approved injectable treatment for cellulite.
- The efficacy of Qwo was established in two identical, randomized, double-blind, placebo-controlled studies in adult women with cellulite (study 1: N = 423; study 2: N = 420). The primary endpoint was the proportion of 2-level multi-component responders at day 71 post-randomization. A 2-level multi-component responder was defined as having an improvement of at least 2 levels of cellulite severity from baseline on both the Clinician Reported Photonumeric Cellulite Severity Scale (CR-PCSS) and the Patient Reported Photonumeric Cellulite Severity Scale (PR-PCSS) in the target buttock.
 - In study 1, the primary endpoint was met in 8% of Qwo patients vs. 2% with placebo (adjusted treatment difference: 6; 95% CI: 2, 10).
 - In study 2, primary endpoint was met in 6% of Qwo patients vs. < 1% with placebo (adjusted treatment difference: 5; 95% CI: 2, 8).
- Qwo is contraindicated in:
 - Patients with a history of hypersensitivity to collagenase or to any of the excipients
 - The presence of infection at the injection sites.
- Warnings and precautions for Qwo include hypersensitivity reactions, injection site bruising, and substitution of collagenase products.
- The most common adverse reactions (≥ 1%) with Qwo use were related to the injection site (bruising, pain, nodule, pruritus, erythema, discoloration, swelling, and warmth).
- Qwo is injected subcutaneously at a dose of 0.84 mg per treatment area. Treatment should be repeated every 21 days for 3 treatment visits.
 - A treatment area is defined as a single buttock receiving up to 12 injections, 0.3 mL each (up to a total of 3.6 mL), of Qwo.
 - A treatment visit may consist of up to 2 treatment areas.
 - Refer to the Qwo drug label for additional administration recommendations.
- Endo is expected to make Qwo available at aesthetic healthcare practitioner's offices starting in spring 2021. Qwo will be available as a 0.92 mg or 1.84 mg lyophilized powder in single-dose vials.