Optum Rx®

NexoBrid® (anacaulase-bcdb) – New orphan drug approval

- On December 29, 2022, MediWound announced the FDA approval of NexoBrid (anacaulase-bcdb), for eschar removal in adults with deep partial thickness (DPT) and/or full thickness (FT) thermal burns.

- The safety and effectiveness of NexoBrid have not been established for treatment of:

    - Chemical or electrical burns
    - Burns on the face, perineum, or genitalia
    - Burns on the feet of patients with diabetes mellitus or on the feet of patients with occlusive vascular disease
    - Circumferential burns
    - Burns in patients with significant cardiopulmonary disease, including inhalation injury.

- NexoBrid is not recommended for wounds contaminated with radioactive and other hazardous substances to avoid unforeseeable reactions with the product and an increased risk of spreading the noxious substance.

- NexoBrid is a botanical drug product containing proteolytic enzymes. The mixture of enzymes in NexoBrid dissolves burn wound eschar.

- The efficacy of NexoBrid was established in two studies. Study 1 was a randomized, controlled, assessor-blinded, 3-arm study, comparing NexoBrid, standard of care (SOC), and gel vehicle treatment in 175 patients with DPT and/or FT thermal burns of 3% to 30% BSA. SOC included both surgical and non-surgical methods for eschar removal per the investigators' discretion. NexoBrid was compared to gel vehicle for the incidence of ≥ 95% eschar removal at the end of the topical treatment period and was also compared with SOC for the incidence of surgical eschar removal (tangential, minor, avulsion, Versajet and/or dermabrasion excision) and time to eschar removal.

    - The incidence of ≥ 95% eschar removal at the end of the topical treatment period was 93% for NexoBrid and 4% for gel vehicle (treatment difference 89, 95% CI: 74, 96).
    - The incidence of surgical eschar removal and time to ≥ 95% eschar removal for the NexoBrid and SOC groups were 4% and 72% for NexoBrid and SOC, respectively (treatment difference -68, 95% CI: -78, -56). The estimated median time to ≥ 95% wound closure for all target wounds on a patient was 31 days for the NexoBrid arm and 36 days for the SOC treatment arm.

- Study 2 was an open-label, randomized, two-arm study, comparing NexoBrid to SOC treatment in 97 patients with DPT and/or FT thermal burns of 5% to 24% BSA. The efficacy assessments were analyzed on DPT burns only. The primary endpoint was the incidence of surgical eschar removal (tangential, minor, avulsion, Versajet and/or dermabrasion excision).

    - The incidence of excision for eschar removal (per wound) was 15% and 63% for NexoBrid and SOC, respectively (treatment difference -47, 95% CI: -59, -34). The incidence of excision for eschar removal (per subject) was 22% and 77%, respectively (treatment difference -55, 95% CI: -71, -38).
    - In randomized patients, the estimated median time to ≥ 95% wound closure was 33 days for the NexoBrid arm and 24 days for the SOC treatment arm.

- NexoBrid is contraindicated in patients with:

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  - Known hypersensitivity to anacaulase-bcdb, bromelain, pineapples, or to any of the other components.
  - Known hypersensitivity to papayas or papain because of the risk of cross-sensitivity.

- Warnings and precautions for NexoBrid include hypersensitivity reactions, pain management, proteolytic injury to non-target tissues, and coagulopathy.

- The most common adverse reactions (> 10%) with NexoBrid use were pruritus and pyrexia.

- NexoBrid is applied as a 3 mm thick layer (approximate thickness of a tongue depressor) to an area of up to 15% body surface area (BSA) in one application. If the wound area is more than 15% BSA, NexoBrid should be applied in 2 separate sessions (eg, treat up to 15% BSA in one session and up to 5% BSA in a second session). The second application should be applied 24 hours after the first application to the same or new burn wound area. The total treatment area must not exceed 20% BSA (40 grams of NexoBrid lyophilized powder) across two treatment sessions.

  - NexoBrid is only to be administered by a healthcare provider.
  - Refer to the NexoBrid drug label for complete dosing and administration recommendations.

- MediWound plans to launch NexoBrid in the second quarter of 2023. NexoBrid will be available as a 8.8% topical gel.

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