Safe and Effective Standards of Care

Supporting the administration of T-VEC for patients with advanced melanoma in the outpatient oncology setting

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BACKGROUND: Talimogene laherparepvec (T-VEC) is the first oncolytic virus (OV) to demonstrate therapeutic benefit for the treatment of advanced melanoma. As a live virus, the use of T-VEC in medical and surgical outpatient clinics posed challenges.

OBJECTIVES: The purpose of this article is to describe the challenges faced when introducing an OV treatment into outpatient clinics and the processes implemented to ensure safety for patients, caregivers, and staff across the care continuum.

METHODS: An interdisciplinary team of experts developed and implemented new practices and workflows to support the administration of T-VEC in the outpatient setting. Clinical staff were educated on this new treatment, its indications and side effects, and the practice standards created to support its use.

FINDINGS: T-VEC posed safety and logistical challenges that were successfully addressed and implemented. To date, 16 patients with locoregionally advanced melanoma have been treated with T-VEC. No adverse events occurred related to preparation or administration, which opens the door for similar therapies in the future.

KEYWORDS
talimogene laherparepvec; T-VEC; oncolytic viruses; virus therapy; cancer

DIGITAL OBJECT IDENTIFIER
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MELANOMA IS SKIN CANCER THAT ARISES FROM THE MELANOCYTES in the epidermis. Its incidence has risen since 1980; an estimated 87,110 new melanomas will be diagnosed in 2017 (American Cancer Society, 2017; Howlader et al., 2013). Surgery cures most early-stage melanoma, but five-year survival rates for late-stage melanoma are as low as 15%–20% (American Cancer Society, 2017). Traditional treatment options for unresectable or metastatic melanoma include palliative surgery, radiation therapy, systemic chemotherapy, and immunotherapy with interleukin-2 (IL-2) (Dummer et al., 2015). Unfortunately, these treatments have had little impact on overall survival, leaving patients with no effective first-line treatment options.

Since 2011, new and more effective immunotherapies have been approved for treating advanced melanoma and have changed clinical management of this disease (Eggermont et al., 2016; Hodi et al., 2010; Ribas et al., 2016). Each of these immunotherapies has a unique mode of action. Immune checkpoint inhibitors use the immune system to attack cancer cells while ignoring healthy cells. Common checkpoint inhibitors used to treat melanoma are cytotoxic T-lymphocyte-associated protein-4 (CTLA-4) inhibitors, such as ipilimumab (Yervoy®), and programmed cell death protein 1 (PD-1) inhibitors, such as pembrolizumab (Keytruda®) and nivolumab (Opdivo®). CTLA-4 and PD-1 inhibitors induce antitumor immune responses by regulating T-cell activation and proliferation (McDermott et al., 2014; Papaioannou, Beniata, Vitsos, Tsitsilonis & Samara, 2016). As single agents, ipilimumab and pembrolizumab have each shown increased overall survival (Hodi et al., 2010; Robert et al., 2015; Schadendorf et al., 2015). Studies examining combination treatments using ipilimumab and nivolumab, a PD-1 inhibitor, and ipilimumab with dacarbazine, a chemotherapy, resulted in longer progression-free survival and higher response rates, but patients experienced higher incidences of grade 3 or 4 adverse events (Larkin et al., 2015; Postow et al., 2015; Robert et al., 2011). For patients with advanced disease, the risk of enduring severe side effects may outweigh the survival benefit that these treatments offer.

Oncolytic Viruses

Oncolytic viruses (OVs) are emerging as vital agents in cancer treatment. Because of their intrinsic characteristics, viruses can be capitalized on to