LOW-VALUE DRUG

Prostate Cancer Treatment with Unclear Efficacy

Hitting the market as the first cancer "vaccine" more than a decade ago,[i] sipuleucel-T (Provenge™) held great promise for men with asymptomatic or minimally symptomatic metastatic castration-resistant prostate cancer. However, flaws in the clinical trial that led to Provenge's FDA approval in 2010, along with clinical evidence that has emerged since then, cast doubts about Provenge's continued use in this patient population. Given the serious efficacy questions and the drug's high cost, NCH clinical experts are sharing evidence about Provenge with oncology practices.

Flawed Trial Designs Contribute to Uncertainty

At the time of its original clinical trials, Provenge was among the few therapies being considered to treat metastatic castration-resistant prostate cancer, so even small improvements were promising. However, with many more treatment options now available, it makes sense to examine Provenge with a critical eye.

Data from its phase three IMPACT trial, summarized in the table below, reveal that while patients did show an improvement in overall survival (OS), there was no significant decline in PSA levels—a typical indicator of efficacy for prostate cancer therapies—or an increase in time to disease progression.

Even more concerning was the trial design itself. For example, researchers provided portions of both the Provenge group and the placebo group with docetaxel, which has proven survival benefit, but did not do so consistently. In the Provenge group, 57.2% of patients received it while only 50.3% of patients received it in the placebo group. In addition, the initiation of docetaxel was delayed by 1.6 months in the placebo group.[ii] Therefore, it's likely that these issues prevented the placebo group from achieving OS rates comparable to those of the Provenge group.

	Provenge	Placebo
Number of patients	311	153
Median overall survival	25.8 months	21.7 months
Time to disease progression	3.7 months	3.6 months
PSA reduction of at least 50% on two visits at least two weeks apart n (%)	8 (2.6%)	2 (1.3%)

[i] Clin Cancer Res (2011) 17 (11): 3520–3526. https://doi.org/10.1158/1078-0432.CCR-10-3126

[ii] N Engl J Med 2010; 363:411-422 doi: 10.1056/NEJMoa1001294

Lack of evidence due to flawed trial designs call Provenge's usage into question.

A more recent trial, PROCEED, showed similar small improvements in OS. But like the IMPACT trial, patients in the PROCEED trial received additional anticancer treatments, such as abiraterone, enzalutamide and cabazitaxel. Therefore, it's likely that, again, the additional treatments contributed to the improvement in survival rates.

In the absence of compelling data that Provenge is effective to treat metastatic castration-resistant prostate cancer, along with its high cost—Medicare & Medicaid Services lists an average sales price of $55,115 for each infusion[iii]—NCH recommends against the use of Provenge.

Because the FDA-approved immunotherapy is still recommended by some organizations for a very narrow indication,[iv] NCH has begun sharing a white paper with network providers and in-house pharmacists that provides details about the data and trial flaws. If your health plan would like to review this white paper, please email us at connect@newcenturyhealth.com.

[iii] Centers for Medicare & Medicaid Services: Medicare. Medicare Part B Drug Average Sales Price. 2022 ASP Drug Pricing Files. Medispan NDC data. Updated 12/14/2022

[iv] National Comprehensive Cancer Network. Prostate cancer (version 4.2022). https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf