Criteria For Non-formulary Use of an Implantable Leuprolide Delivery System (Viadur®)

VHA Pharmacy Benefits Management Strategic Healthcare Group
and the Medical Advisory Panel

These criteria were based on the best clinical evidence currently available. The recommendations in this document are dynamic, and will be revised as new clinical information becomes available. This guidance is intended to assist practitioners in providing consistent, high quality, cost effective drug therapy. It is not intended to interfere with clinical judgment; the clinician must ultimately decide the course of therapy based on individual patient situations.

The Viadur® implantable leuprolide delivery system is a sterile nonbiodegradable osmotically driven system that delivers leuprolide at a controlled rate for 12 months. It was approved in March of 2000 for the palliative treatment of advanced prostate cancer.

Criteria for use in VA patients

Patients with metastatic prostate cancer who require hormonal manipulation therapy for at least 12 months and have refused or are not candidates for an orchiectomy

AND

Have demonstrated tolerability and a response* to a long acting injectable LHRH agonist

AND

Have limited access to appropriate medical care because of geographical distances and/or transportation difficulties and have planned clinic visits or access to medical care less often than quarterly

Response: A decrease in serum testosterone to castrate levels (<50 ng/dL), a decreased and stable PSA, and symptomatic improvement

Dosage:
All patients receive one implant containing the equivalent of 65mg of leuprolide every 12 months. The implant is inserted subcutaneously into the inner aspect of the upper arm via an incision into the crease between the biceps and the triceps. At the end of 12 months the implant is removed and a new implant is inserted at the same site or on the contralateral arm.

Tolerability:

Precautions
All LHRH agonists cause an increase in serum testosterone during the first 1-2 weeks of therapy. This increase may exacerbate symptoms or cause the onset of new symptoms (e.g. bone pain, ureteral obstruction, neuropathy).

Safety
Incidence of Adverse Events

Hot Flashes*	67.9%	Asthenia	7.6%
Gynecomastia*	6.9%	Headache	4.6%
Testicular atrophy or pain*	3.8%	Urinary urgency	3.8%
Impotence*	2.3%	Weight gain	2.3%
Sweating*	5.3%	Peripheral Edema	3.1%
		Extremity pain	3.1%
		Diarrhea	2.3%

*Expected pharmacologic consequence of testosterone suppression

Local Insertion-site reactions: (Mild/transient and resolved within 2 weeks)
Bruising in 40%, pain, burning, itching, bleeding, edema

Monitoring:
Response should be monitored by periodically measuring serum testosterone concentrations and serum PSA. Improvement in any disease symptoms is expected as serum testosterone levels fall below castrate level.

References:

Fowler JE, Gottesman JE, Reid CF, Andriole GL, Soloway MS. Safety and efficacy of an implantable leuprolide delivery system in patients with advanced prostate cancer. J Urol2000;164(Part 1 of 2):730-734.

Fowler JE, Flanagan M, Gleason DM, Klimberg IW, Gottesman JE, Sharifi R, for the Viadur Study Group. Evaluation of in implant that delivers leuprolide for 1 year for the palliative treatment of prostate cancer. Urology 2000;55:639-642.

Fowler JE on behalf of the Viadur Study Group. Patient-reported experience with the Viadur 12-month leuprolide implant for prostate cancer. Urology 2001;58:430-434.

Viadur (leuprolide acetate implant) Product Information. Bayer 2002.

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