



Acceptance Criteria

After Biopsy | DECIPHER PROSTATE BIOPSY

- **ALL** Gleason Scores
- **ALL** PSA Values
- **ALL** Stages

After Radical Prostatectomy | DECIPHER PROSTATE RP

- **ALL** Gleason Scores
- **ALL** PSA Values*
- **ALL** Stages

*Undetectable, rising, and persistently elevated PSA

Decipher Prostate is indicated for non-metastatic men who have not received pelvic radiation or ADT prior to biopsy or RP, and have a life expectancy of 10 years or greater.

Medicare Coverage Criteria

Decipher® is covered for men with prostate cancer:

With localized or biochemically recurrent adenocarcinoma of the prostate (i.e., no clinical evidence of metastasis) who have a life expectancy of greater than or equal to 10 years if they are a candidate for and are considering (or being considered for) at least 1 of the following:

- Conservative management and yet would be eligible for definitive therapy (radical prostatectomy (RP), radiation or brachytherapy), or;
- Radiation therapy and yet would be eligible for the addition of a brachytherapy boost, or;
- Radiation therapy and yet would be eligible for the addition of short-term androgen deprivation therapy (ADT), or;
- Radiation therapy with short-term ADT yet would be eligible for the use of long-term ADT, or;
- Radiation with standard ADT yet would be eligible for systemic therapy intensification using next generation androgen signaling inhibitors or chemotherapy, or;
- Observation post-prostatectomy yet would be eligible for the addition of post-operative adjuvant radiotherapy, or;
- Salvage radiotherapy post-prostatectomy yet would be eligible for the addition of ADT

The following criteria must also be met for coverage:

- The assay is performed on formalin-fixed paraffin embedded (FFPE) prostate biopsy tissue with at least 0.5 mm of linear tumor diameter or FFPE tissue from a prostate resection specimen, and;
- Result will be used to determine treatment according to established practice guidelines, and;
- Patient has not received pelvic radiation or ADT prior to the biopsy or prostate resection specimen, and;
- Patient is monitored for disease progression according to established standards of care.

