Personalized Medicine testing recommendations for:

Prostate

Early Stage

When and what should be tested?

- Treatment eligible
- At initial diagnosis

FDA/NCCN approved

- Risk Stratification: Selected Advanced Tools for Localized Prostate Cancer
  - Decipher - 22-gene genomic classifier
  - ArteraAI Prostate – Multimodal artificial intelligence

- Inquire about known high risk germline mutations and family history. Perform somatic and/or germline testing as appropriate for clinically localized, regional prostate cancer
- Germline panel: BRCA1, BRCA2, ATM, PALB2, CHEK2, HOXB13, MLH1, MSH2, MSH6, PMS2
- Somatic Panel: BRCA1, BRCA2, ATM, PALB2, FANCA, RAD51D, CHEK2, CDK12

Emerging

Informational Considerations

Regular monitoring of PSA levels is required as standard of care. Relevant Testing Panel:
- Germline Panel: BRCA2, ATM, BRCA1, CHEK2, PALB2, GEN1, RAD51D, MLH1, MSH2, MSH6, PMS2, HOXB13
- Somatic Panel: Genes that encode proteins responsible for DNA damage repair via homologous recombination, including ATM, BRCA1/2, and CHEK2 (among others), as well as genes that encode proteins involved in mismatch repair

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Personalized Medicine testing recommendations for:

Prostate

Node Positive and Stage IV Newly Diagnosed and Recurrent Disease (somatic)

When and what should be tested?

- Treatment eligible
- Node positive and Stage IV
- At initial diagnosis or upon progression
- Patients with hereditary risk syndromes
- Blood sample for germline testing
- Tissue sample for somatic testing
- Consider liquid biopsy if lack of tissue

FDA/NCCN approved

- HRRm/Homologous Recombination Repair gene mutation (BRCA1, BRCA2, ATM, BARD1, BRIP1, CDK12, CHEK1, CHEK2, FANCA, FANCL, HOXB13, PALB2, RAD51B, RAD51C, RAD51D, RAD54L, ATR, MLH1, MSH2, MSH6, PMS2, MRE11A, NBN)
- MSI/dMMR
- NTRK
- TMB
- BRAF V600E
- RET gene rearrangement
- HER2

Emerging

- ZNF 750 is a novel prognostic marker in metastatic prostate cancer
- MRD

Informational Considerations

- Traditional histologic features
- AR-V7 splice variant testing for progression on prior hormonal therapy
- For regional or met disease ≥ N1 and Gleason score ≥ 7 or high risk:
  - Consider germline testing
- For treatment-naïve metastatic and Gleason score ≥ 7:
  - Consider somatic testing; retest after 2-3 lines of therapy
- For castrate-resistant:
  - Consider comprehensive NGS if failed early on treatment; should include TMB, MSI, NTRK, BRCA 1/2

Regular monitoring of PSA levels is required as standard of care. Relevant Testing Panel:

- Germline Panel: BRCA2, ATM, BRCA1, CHEK2, PALB2, GEN1, RAD51D, MLH1, MSH2, MSH6, PMS2, HOXB13
- Somatic Panel: Genes that encode proteins responsible for DNA damage repair via homologous recombination, including ATM, BRCA1/2, and CHEK2 (among others), as well as genes that encode proteins involved in mismatch repair

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Personalized Medicine testing recommendations for:

Bladder

Stage II/IIIA

When and what should be tested?

- At time of initial diagnosis
- Tissue sample preferred
- Consider liquid biopsy if there is a lack of tissue

Who should be tested?

- All treatment eligible patients
- Performance status of ECOG 0-2
- Consider germline testing and genetic counselor referral especially if younger age at presentation (< 45 years) or family history of colon/endometrial cancer

FDA/NCCN Approved

- n/a

Emerging

- NGS for patients with early bladder cancer for possible active surveillance based on RETAIN BLADDER TRIAL. Stage II-IIIA
- Ct DNA during and after neoadjuvant chemotherapy.
- MRD

Informational considerations

- ERCC-1 expression (cisplatin sensitivity)
- ERCC2 (cisplatin sensitivity)

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Personalized Medicine testing recommendations for:

Bladder

Stage IIIB/IV

When and what should be tested?

- At time of initial diagnosis
- Tissue sample preferred
- Consider liquid biopsy if there is a lack of tissue

Who should be tested?

- Treatment eligible
- Performance status of ECOG 0-2
- Consider germline testing and genetic counselor referral especially if younger age at presentation (< 45 years) or family history of colon/endometrial cancer

FDA/NCCN Approved

- Consider comprehensive NGS panel if insurance allows (including NTRK*)
- MSI/dMMR
- PD-L1
- TMB
- FGFR 3
- NTRK
- PIK3CA
- ERBB2/HER2
- CDKN2A

Based on tumor-agnostic approval

- RET gene rearrangement
- BRAF V 600 E

Emerging

- NECTIN4 expression

Informational considerations

- ERCC-1 expression (cisplatin sensitivity)
- ERCC2 (cisplatin sensitivity)

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