Optimizing First-Line Management of Metastatic Hormone-Sensitive Prostate Cancer

Developed in collaboration with the AUA, Astellas, and Pfizer Oncology

American Urological Association

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INTRODUCTION

Phase III randomized clinical trials have demonstrated that adding an androgen receptor pathway inhibitor (APRI) or an APRI+docetaxel to androgen deprivation therapy (ADT) improves survival outcomes for patients with metastatic hormone-sensitive prostate cancer (mHSPC)[i] [1] Key clinical trials that support these conclusions are listed in Table 1.[2-9]

Trial	Treatments	Overall Survival (OS) Outcomes	Key Finding
STAMPEDE Trial (1719 patients with locally advanced or metastatic disease starting long-term ADT)	ADT alone vs. ADT plus abiraterone (1000 mg daily) + prednisolone (5 mg daily)	OS 3 years: 83% with ADT + Abiraterone vs. 76% with ADT alone (P<0.001)	Adding abiraterone to ADT improves survival in locally advanced or mHSPC
LATITUDE Trial (1199 patients with mHSPC)	ADT alone vs. ADT plus abiraterone 1000 mg once daily	Median OS at 30.4 months: not reached for ADT + Abiraterone vs. 34.7 months for ADT alone (P<0.001)	Adding abiraterone to ADT significantly improves survival mHSPC
TITAN Trial (525 patients with mHSPC)	ADT alone vs. ADT plus apalutamide (240 mg daily)	2-year OS: 82.4% for ADT plus apalutamide vs. 73.5% for ADT alone (P<0.005)	Adding apalutamide to ADT improves survival in both high- and low-volume mHSPC.
ENZAMET Trial (1125 men with mHSPC)	ADT plus enzalutamide (160 mg daily) vs. ADT plus "standard care" (nonsteroidal anti-androgen [bicalutamide, flutamide, nilutamide])	OS at 3 years: 80% for enzalutamide vs. 72% for standard care. After a median follow-up of 34 months, there were 102 deaths for enzalutamide vs 143 for standard care (P= 0.002)	Adding enzalutamide to ADT improves survival
ARASENS Trial (1306 patients with mHSPC)	ADT plus darolutamide (600 mg twice daily) and docetaxel (triplet therapy) vs. ADT with docetaxel alone	OS at 4 years: 62.7% months (triplet therapy) vs. 50.4 months (ADT + docetaxel alone). Hazard ratio for death 0.68 (P<0.001)	Darolutamide docetaxel triplet therapy improves survival in high-volume disease
PEACE-1 Trial (1173 patients with mHSPC)	"Standard of care" (SOC; ADT alone or with docetaxel), SOC + abiraterone, or SOC + abiraterone + radiotherapy	The addition of abiraterone and docetaxel significantly improved OS (P=0.02) and radiographic progression free survival (rPFS; P<0.001)	Combining ADT with docetaxel and abiraterone improves survival in patients with mHSPC
ARCHES Trial (1150 men with mHSPC)	ADT plus either enzalutamide 160 mg/day or placebo	Enzalutamide plus ADT reduced risk of death by 34% vs placebo plus ADT (P<0.001).	The addition of enzalutamide to ADT significantly improves survival.
ARANOTE Trial (669 patients with mHSPC)	ADT plus either darolutamide or placebo	Darolutamide reduced the risk of radiological progression by 46% (P<0.0001). Changes in overall survival were not statistically significant.	The addition of darolutamide to ADT significantly reduces the risk of progression or death

National treatment guidelines for mHSPC provide recommendations that are based on this evidence. The 2023 Advanced Prostate Cancer guidelines from the American Urological Association (AUA) and Society for Urologic Oncology provide a strong recommendation that patients with mHSPC should be treated with ADT in combination with an APRI or docetaxel.[10] Similarly, treatment guidelines from the National Comprehensive Cancer Center Network© (NCCN©; version 2.2026) for the treatment of mHSPC call for first-line treatment with combination therapy consisting of ADT combined with an androgen receptor pathway inhibitor (ARPI); chemotherapy with docetaxel may be added as triple therapy.[ii][11] Recommended APRIs include abiraterone, darolutamide, apalutamide, and enzalutamide.[11]

Although combination therapy improves survival and is recommended by national guidelines, available evidence indicates that many patients do not receive this treatment approach. For example, insurance claims data indicate that more than one third of mHSPC patients in the United States are initially treated with only ADT.[1]

In a survey conducted from 2018 to 2022, physicians reported that only 30.3% of mHSPC patients received combination therapy as first-line treatment[1]. Some patients (26.9%) who were initially treated with ADT alone were subsequently treated with combination treatment; however, more than 40% were never treated with combination therapy.[1]

Reasons that were cited by physicians for not prescribing an ARPI included the following:[1]

- An ARPI would need to have a better/more tolerable side-effect profile/fewer adverse events than my chosen regimen.
- I would need to have seen clinical trial evidence of survival improvements on ARPIs including a wider range of patients with prostate cancer.
- ARPIs would need to be reimbursed by the patient's insurance.
- Patients would have to have no financial constraints restricting ARPI usage (e.g., able and willing to pay the copayment).

Another study that focused on interviewing physicians who treat patients with mHSPC identified several facilitators and barriers that influence first-line use of combination therapy (Table 1).[12]

i mHSPC is sometimes referred to as metastatic castration sensitive prostate cancer (mCSPC).
ii Combination therapy is sometimes referred to as treatment intensification.

Table 1. Factors that Act as Facilitators or Barriers for First-Line Combination Therapy

Key Facilitators	Key Barriers
• Good knowledge of clinical trial data • Ability to translate knowledge into practice • Anticipated regret about losing the best chance at improving survival • Habit of intensifying first-line treatment • Tendency not to limit intensification solely based on age, performance status, and/or comorbidities, other than in exceptional cases* • Good interdisciplinary collaboration† • Belief in urologist role in treatment intensification† • Administrative support to address cost • Clinical staff to facilitate treatment intensification* • Minimal treatment cost impact	• Knowledge gaps • Anticipated regret over losing treatment options for later • Anticipated regret over side effects and negative impact on quality of life • Tendency to restrict treatment intensification to high-volume or severe disease • Habit of not intensifying first line treatment† • Delayed urologist referral to oncologist* • Cost of treatment intensification • Insufficient clinical support†
Peripheral Facilitators	**Peripheral Barriers**
• Confidence in first-line treatment intensification • Comfort with managing treatment intensification • Clinical pathways	• Prioritizing preserving quality of life • Low-intensifier peer environment† • Patient's disease not to intensify

**Facilitator or barrier more frequently experienced by oncologists.*
†Facilitator or barrier more frequently experienced by urologists.

AUA Member Focus Groups

To review current practice patterns in various healthcare settings and identify barriers and best practices to improve utilization of combination therapy for mHSPC, AUA consulted a panel of subject matter experts to conduct three virtual focus groups with the following participants:

- Group 1: Six urologists who were high utilizers of combination therapy (defined as at least 50 percent of patients with mHSPC utilizing first line combination therapy).
- Group 2: Five urologists who were low utilizers of combination therapy (defined as less than 50 percent of patients with mHSPC utilizing first line combination therapy).
- Group 3: Seven advanced practice providers (APPs).

All focus group participants were from the United States and were currently managing patients with mHSPC. They represented a variety of practice settings including, two solo practices, eight urology group practices, two multi-specialty group practices, five academic/hospitals, and one person practicing in a managed care setting. Urologic care providers that are high utilizers of first-line combination therapy were more likely to work in private practices compared to academic/hospital-based practices.

Participants reported that the main barriers to utilizing first-line combination therapy in patients with mHSPC are:

- The financial burden to patients, prior authorization and lack of insurance coverage approval (main barrier)
- Urologists being overwhelmed with the number of therapies that are available now
- Uncertainty about what is best for patients and when combination therapy should be started for patients/waiting to intensify
- Habit of starting patients on ADT or first-generation anti-androgens
- Management of treatment side effects, especially in elderly patients
- Resource utilization and operational challenges for combination therapy and medical oncologists being better set up to deliver this therapy
- Lack of knowledge by urologists of the new data that is currently available in this space

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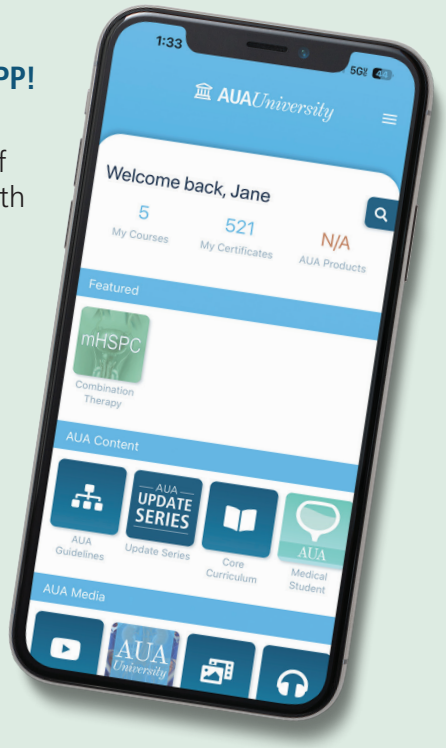

A DEEPER DIVE: CONVERSATIONS WITH PRACTITIONERS

To gain a deeper understanding of the strategies and process used by practice sites with high levels of first-line combination therapy, AUA interviewed practitioners from three practice sites: Guthrie Medical Group (PA), Keystone Urology Specialists (PA), and Southeast Urology Network (TN). The goal of the interviews was to identify best practices that urologic healthcare providers can implement to improve the care of advanced prostate cancer patients. Each interview included members from the multi-disciplinary team and covered a range of topics including treatment selection, management of adverse events, provider roles, and strategies for addressing patient financial issues.

KEY FINDINGS

- All three practices emphasize that early and consistent use of combination therapy improves survival and quality of life. They use combination therapy aligned with NCCN Guidelines© for almost all patients with mHSPC.
  - Most patients receive ADT with an ARPI, and patients with high-risk/high-volume disease often receive triplet therapy (ADT + ARPI + docetaxel).
  - ADT alone is rarely used and generally is only utilized for very frail patients.
- Treatment decisions are multidisciplinary, patient-centered, and influenced by disease volume/risk, cardiovascular health, and patient preference.
- Each practice has dedicated staff (social workers, in-office dispensary coordinators, and/or navigators) to manage financial issues for patients and support access to combination therapy by working to obtain prior authorizations from payers and seeking grants from foundations to help cover copay/coinsurance amounts.
- There is variability in whether urologists or medical oncologists are most likely to prescribe ARPIs and manage patients with mHSPC, but in either case, practices stress the importance of collaboration with all team members. When triplet therapy is prescribed, medical oncologists manage the docetaxel component.
- Practices are proactive in educating patients about potential side effects and how they can be managed. However, all practices emphasized that discontinuation rates are low because patients prioritize survival and are almost always willing to tolerate the side effects.
- Use of ARPIs should be individualized based on patient factors such as comorbid conditions and medication use. In some cases, treatments may need to be modified or additional medications can be added to assist with management of side effects. Patients with underlying cardiovascular conditions may be comanaged with a cardiologist to optimize outcomes.
- Having a physician at the practice who specializes in the treatment of advanced prostate cancer helps to optimize treatment approaches with guideline-aligned care and access to novel therapies.
- Referral to specialized centers is recommended for practices that have challenges implementing combination therapy aligned with NCCN Guidelines, particularly when resources or ability to specialize are limited.

CASE STUDY: GUTHRIE MEDICAL GROUP

Guthrie Medical Group Interviewees

Chalairat Suk-ouichai, MD, MPH
Urologist

Le Wang, MD, PhD
Medical Oncologist and Assistant Professor of Hematology & Oncology

Christopher Pitchford, PA-C
Urology Physician Assistant

Approaches to mHSPC Management

Guthrie Medical group is a multi-specialty group practice located in Sayre, Pennsylvania that serves as a regional specialty care referral center. Several team members are typically involved in the care of patients with mHSPC including a urologist, a medical oncologist, and a radiation oncologist.

Patients typically present to Guthrie's urology department when they have elevated prostate-specific antigen (PSA) levels or urinary symptoms, and urologists initiate diagnostic workups, including biopsies and advanced imaging. If prostate cancer is diagnosed, ADT may be started by the urologists.

Urologists refer patients to medical oncologists if patients have metastatic disease or experience disease progression. Medical oncologists prescribe combination therapy and lead long-term management. Radiation oncologists evaluate definitive local therapy for early-stage prostate cancer or palliative therapy for metastatic cases. Cardiologists are involved in managing patients with high risk of cardiovascular disease. Having clear referral pathways to collaborate with medical oncologists and other providers within the network is critical for ensuring that patients are receiving current evidence-based care safely and effectively.

GUTHRIE MEDICAL GROUP MHSPC PROVIDER ROLES

Provider	Roles
Urologist	• Refers to medical oncology if combination therapy or neoadjuvant/adjuvant therapy is needed
Medical Oncologist	• Manages combination therapy, chemotherapy, and targeted therapy
Radiation Oncologists	• Evaluates for definitive local therapy for localized prostate cancer or palliative therapy for metastatic disease
Social Worker	• Manages financial issues associated with treatment
Clinical Pharmacist	• Provides education to patients regarding medication use
Physician Assistant	• Assists with side effect management

The overwhelming majority of patients with mHSPC are treated with combination therapy. Those with low or moderate risk, low volume disease are treated with ADT and an ARPI while those with high-risk or high-volume disease receive triplet therapy (ADT, an ARPI and docetaxel). "We follow the NCCN Guidelines to guide treatment decision for prostate cancer," notes Dr. Wang.

"We strongly encourage the use of combination therapy and rarely use ADT alone," explains Dr. Wang. "Combination therapy has been the standard for nearly a decade and remains the cornerstone of treatment. NCCN Guidelines advise against monotherapy except in cases of significant frailty." Patients receive ADT alone only if they are extremely frail or have severe comorbidities. Dr. Suk-ouichai confirms this approach, "we have patients who are referred to us who are being treated with ADT alone. When they come to us, we work with medical oncology to get them started on combination therapy."

Treatment selection is guided by age, comorbidities, especially cardiovascular risk, and patient preferences. "Most patients prioritize survival over any side effects. Even when they start to experience these side effects,

our discontinuation rates are low," explains Dr. Suk-ouichai. "Very few patients choose to use a palliative care approach."

A social worker navigates the financial issues related to combination therapy including obtaining prior authorizations and identifying strategies to increase access for uninsured or underinsured patients. There are occasionally delays in approval for newer agents but Dr. Suk-ouichai reports that the social worker generally is able to obtain access for patients. "Having a dedicated staff member has been incredibly helpful for addressing financial barriers."

Strategies to Manage Adverse Events

The patient care team works collaboratively to manage adverse events, and Mr. Pitchford PA-C plays a key role in side effect management. Medications are dispensed from a specialty pharmacy, where patients typically receive medication-related education. However, there is a clinical (non-dispensing) pharmacist on staff who provides an educational session for patients when combination therapy is initiated. The pharmacist provides the patient with information about what to expect during treatment, including anticipated adverse events and management strategies.

The medical oncologist also prescribes additional treatments as necessary to manage adverse events as they arise. For example, chemotherapy-related neutropenia is managed with growth factors and neuropathy is addressed with duloxetine or gabapentin. Adverse events related to ARPIs typically include hot flashes, fatigue, and bone loss; in particular, ARPI-associated bone loss can be mitigated with the use of calcium and vitamin D supplementation, and weight-bearing exercises and managed with RANK ligand inhibitor such as denosumab.

Cardiovascular risks can be challenging to manage. Dr. Wang prioritizes therapies with minimal cardiac toxicity and works closely with cardiologists, especially cardio-oncologists, for those patients with pre-existing heart conditions.

"In my experience, patients tolerate combination therapy well long-term, with minimal concerns about reduced quality of life," reports Dr. Wang. Mr. Pitchford agrees with this assessment; "I don't think I've ever met one who actually elected for palliative or comfort care measures only. So they don't appear comfortable, but it doesn't seem like they're so uncomfortable they're electing for palliative medicine," he observes.

Strategies for Staying Current

There is no formal system for tracking guideline updates; providers independently stay informed through continuing medical education and team collaboration.

"Many of the patients who come to us have already done extensive online research about their condition and they are seeking combination therapy," explains Dr. Suk-ouichai.

CASE STUDY: KEYSTONE UROLOGY SPECIALISTS, MIDLANTIC UROLOGY

Keystone Urology Specialists Interviewees

Paul Sieber MD, FACS
Medical Director Clinical Trials

Jamie Snyder, MA
In-office Dispensary (IOD) Coordinator

Heather Brown, RN
Clinical Research Coordinator

Erica Collins, BSN
Clinical Research Coordinator

Approaches to mHSPC Management

Keystone Urology Specialists is a large group practice with eight urologists based in Lancaster, Pennsylvania, a region with a slightly above-average socioeconomic status. Approximately 70% of their patients are Medicare beneficiaries, and nearly all have some form of insurance coverage. The practice has a high volume of patients with advanced prostate cancer. Patients are commonly referred to Dr. Sieber from other urologists when they have metastatic disease.

Dr. Sieber is Keystone's designated prostate cancer champion. In this role, he oversees the care of patients with advanced disease, coordinating a multidisciplinary team that includes another urologist, a medical oncologist, a radiation oncologist, a physician assistant, an IOD specialist, and a research team that manages involvement with multiple clinical trials. "As the champion, I act as the quarterback on the patient's team, and I can call in the other providers as needed to address various needs as they arise," explains Dr. Sieber. Research coordinators manage patients involved in clinical trials and assist in their transition back to standard-of-care treatment when needed.

KEYSTONE UROLOGY SPECIALISTS MHSPC PROVIDER ROLES

Provider	Roles
Urologist Champion	• Acts as the "quarterback" overseeing treatment for patients with mHSPC
Medical Oncologist	• Manages patients receiving chemotherapy (triplet therapy)
IOD Specialist	• Dispenses medications and helps to navigate financial issues
Research Team	• Oversees patient involvement in clinical trials

Some patients with metastatic disease have been treated with ADT alone prior to being referred to Keystone. However, virtually all patients with mHSPC at Keystone receive combination therapy. "The only situation in which we would not start combination therapy would be if someone was very frail and elderly and already had a very short anticipated lifespan so that we wouldn't expect them to live long enough to experience the benefits of treatment," notes Dr. Sieber. "But unless there are some really extenuating circumstances, we use combination therapy for these patients."

Combination therapy is aligned with NCCN Guidelines and includes triplet therapy (ADT + ARPI + docetaxel) used for high-risk or high-volume disease, and doublet therapy (ADT + ARPI) for low- to moderate-risk disease. Patients receiving triplet therapy have the chemotherapy component of treatment managed by the medical oncologist.

Treatment selection for ARPIs is individualized based on patients' clinical conditions and preferences. Additionally, abiraterone is now available generically, which makes it much more affordable and can be an important factor for some patients.

Adverse Event Management

The team monitors patients closely for the emergence of side effects. "Occasionally there need to be treatment modifications due to side effects, but patients generally tolerate the ARPI medications well,"

reports Dr. Sieber. For example, Dr. Sieber reports that patients are willing to tolerate effects such as hot flashes or muscle weakness because they are more concerned about survival. "I've heard the concerns that starting ARPIs reduces quality of life due to side effects, but the reality is that you are preserving the quality of life by preventing the progression of a painful disease so people on ARPIs stay healthier longer."

Treatments are individualized based on patients' other health conditions. For example, patients who are being treated with anticoagulants are carefully managed in conjunction with cardiologists and may be better able to tolerate certain ARPIs, but should avoid enzalutamide, which can interact with some anticoagulants. On rare occasions, patients cannot tolerate an ARPI due to challenges with liver enzymes or fluid retention in a patient with heart failure. In other cases, adjustments to medications for treating hypertension are sufficient to address fluid retention. Additionally, dose reduction may be appropriate for other adverse events such as fatigue or rash.

Addressing Financial Issues

The practice has established efficient processes for helping patients access medication through foundations and patient assistance programs, minimizing financial barriers. As the IOD Coordinator, Ms. Snyder focusses on filling prescriptions, initiating medication therapy for patients, and addressing financial issues for patients. This includes connecting with foundations that offer grants to patients to help them with out-of-pocket expenses.

"Third-party payers are generally aligned with the NCCN Guidelines and will provide coverage for treatments that follow guideline recommendations," observes Ms. Snyder. According to Ms. Snyder, patients sign a form that allows the practice to apply for grants on their behalf. The IOD first submits the claim to the patient's insurance provider, and the foundation that is offering a grant is entered as the secondary insurance. Therefore, the patient will not have to pay anything out-of-pocket when the medication is dispensed. If a patient is uninsured, Ms. Snyder enrolls them in manufacturer patient assistance programs so that they can obtain access.

Staying at the Forefront of Practice

Approaches to care for prostate cancer have advanced dramatically over the past decade. In addition to being guided by conclusive data regarding which treatments are most effective first-line for mHSPC, several other advances have been implemented. For example, genetic testing for somatic and germline mutations (e.g., BRCA mutation) can now be used to guide the selection of subsequent treatments. Patients with certain mutations are more likely to respond to PARP inhibitors.

As a champion, Dr. Sieber regularly reviews NCCN Guidelines to ensure that he is aligned with the most current recommendations. Additionally, the organization's monthly tumor board meetings regularly include the NCCN Guidelines and updates in their discussions, which helps keep all members current.

However, staying current with the rapidly evolving treatment landscape can be a challenge. "Physicians who were trained more than 10 years ago did not learn about these treatment options as part of their training," observes Dr. Sieber. "For patients to receive optimal evidence-based care, it is essential that they are treated by someone who is familiar with newer treatment approaches," he stresses.

Dr. Sieber recognizes that it can be difficult for urologists to stay current with all aspects of care. "Not everybody is going to be an expert in everything or have the resources to manage every treatment, particularly if they aren't specializing in prostate cancer." In those situations, Dr. Sieber recommends that providers refer patients to others who do specialize and are connected with resources that allow for the delivery of care aligned with NCCN Guidelines. "Earlier treatment with combination therapy matters. People live longer and suffer less. So prescribing ARPIs yourself or referring your patients to someone who does is critical for your patient outcomes."

CASE STUDY: SOUTHEAST UROLOGY NETWORK

Southeast Urology Network Interviewees

Mark Saslawsky, MD
Urologist

Tosha Mote, CMA
Advanced Prostate Cancer Navigator

Approaches to Treatment of mHSPC

Dr. Saslawsky is a prostate cancer champion at the practice who works in Southeast's Advanced Prostate Cancer (APC) clinic, a small group practice in Memphis, Tennessee. The APC clinic's patient care team also includes three physicians and a nurse practitioner. They collaborate with other specialists, such as medical oncologists or radiation oncologists, as needed.

New patients with elevated PSAs are initially seen by Southeast's nurse practitioner to establish care and obtain a current PSA level. If the PSA is confirmed to be elevated, the patient typically undergoes a prostate biopsy. Should the biopsy confirm a prostate cancer diagnosis, the urologist who performed the biopsy will treat the patient according to NCCN Guidelines. If patients present with or develop metastatic disease (typically identified with a PSMA scan), they are transferred to the APC clinic where Dr. Saslawsky and Ms. Mote collaborate to provide the most up-to-date evidence-based treatment options for the patient.

As the APC navigator, Ms. Mote serves as a dedicated point of contact for patients and their families throughout the complex journey of prostate cancer treatment. Her role involves providing education, support, and coordination of care for individuals diagnosed with advanced or metastatic prostate cancer. "I work closely with the urologist and multidisciplinary team to help patients understand their diagnosis, explore treatment options, navigate insurance and financial resources, and schedule follow-up appointments and consultations," she explains. "My goal is to ensure each patient receives timely, personalized, and comprehensive care while minimizing barriers and enhancing their overall experience."

SOUTHEAST UROLOGY NETWORK MHSPC PROVIDER ROLES

Provider	Roles
Nurse Practitioner	• Sees new patients with elevated PSAs
Urologist	• Biopsies patients and treats in accordance with NCCN guidelines
APC Urologist	• Acts as the advanced prostate cancer champion • Treats patients with metastatic disease throughout their cancer journey
APC Navigator	• Provides education, support, and coordination of care

Virtually all patients with mHSPC receive doublet or triplet therapy, in alignment with NCCN Guidelines. Patients receive ADT alone only if they are frail or refuse combination therapy. Patients receive triplet therapy if they have high risk or high-volume disease; others are managed with combination therapy with ADT and an ARPI. "We try to start them on the optimal medication combination. There's pretty robust data showing that the ARPIs provide benefits for overall survival, as well as radiographic progression, and delay the initiation of secondary and tertiary lines of therapy." Therefore, treating patients with combination therapy is a priority. The selection among ARPIs may be based on the patient's preference regarding whether to use an oral or an injectable medication, as well as the anticipated level of compliance with various regimens.

As advanced prostate cancer champions, Dr. Saslawsky and his colleagues in the clinic manage patients throughout their mHSPC journey. Patients who are candidates for triplet therapy are co-managed with a medical oncologist who manages the administration of docetaxel.

Strategies to Manage Adverse Events

Adverse effects associated with treatment are managed proactively. "We work really hard to set expectations for treatment upfront and explain the side effects to patients, and then we maintain an open door-type relationship with patients when issues arise. That curtails the issue of nonadherence." explains Dr. Saslawsky. Patients who are at high risk for cardiovascular adverse events are managed in

collaboration with cardiologists. "ADT as well as ARPIs have side effects; we discuss the specific side effects of each agent with patients and then monitor for them." In some cases the side effects can be treated with another agent and in others, a dose reduction may be appropriate.

Patients prioritize survival over any side effect burden and there is a very low rate of treatment discontinuation due to toxicity. "Occasionally we have a patient who, for one reason or another cannot tolerate the ARPI and whose PSA becomes nondetectable on combination therapy. In those cases we may continue them on ADT alone, and perhaps rechallenge them with a different ARPI at some later point," notes Dr. Saslawsky.

Benefits of an APC Clinic and Champion Practice Structure

Treatment of advanced prostate cancer has changed dramatically over the past several years and having an APC clinic structure helps to ensure that patients receive the most current, evidence-based care available. "Changes have included the ARPI agents as well as novel diagnostic approaches, immunotherapy, genetic screening, PARP inhibitors, and expanded chemotherapy options," observes Dr. Saslawsky.

Having a champion who is committed and focused on the care of patients with advanced prostate cancer helps the practice remain at the forefront of evolving treatment. "A designated champion who specializes in the care of patients with advanced prostate cancer is vital for timely diagnosis, personalized treatment planning, and comprehensive management, which are all essential for improving outcomes and quality of life for individuals facing this complex disease," emphasizes Dr. Saslawsky. In addition to providing cutting-edge approaches to treatment, the APC also utilizes data mining to track patients and ensure that their treatment and management are being optimized.

Southeast uses a Specialty Networks protocol, which is embedded within the practice's EMR. These protocols are updated anytime a new medication is approved or there is a change to treatment guidelines. Dr. Saslawsky also regularly participates in continuing education programs and is involved with professional associations to ensure that he is practicing with the most current information available.

The APC has also implemented an IOD to streamline continuity of care and increase convenience for patients. It also provides financial benefits to the clinic. "We follow state regulations and it is within our scope of practice to manage the IOD and we do not have to have a pharmacist or pharmacy technician on staff," observes Dr. Saslawsky. The IOD stocks the medications that are involved in the care of advanced prostate cancer and is able to dispense them directly to patients.

Dr. Saslawsky acknowledges that it may not be feasible for all practices to have a urologist in this dedicated role and recommends that providers form collaborations and refer patients as needed. "Providers who only see a few patients with metastatic disease may be able to best serve their patients by collaborating with other providers and referring to someone who specializes in this area and can ensure that patients receive care aligned with national treatment guidelines," he explains.

Managing Financial Issues

Obtaining third-party payer coverage for treatment is important for ensuring access to ARPI treatment. A dedicated clinic helps to provide centralization not just for optimizing treatment but also for centralizing knowledge about how to obtain access for the medications. "An APC clinic provides the opportunity for the patient to receive that dedicated care that it takes to manage their disease state to the most effective degree."

The majority of Southeast's patients are Medicare beneficiaries; they have a range of economic backgrounds but a substantial proportion are below the federal poverty level.

The APC clinic has a nurse navigator who helps facilitate medication access. "We explore all our options to help ensure patients get the treatment they need with as little financial burden as possible," explains Ms. Mote. Many patients have Medicare Part D; patient out-of-pocket costs through Part D have been lowered in recent years, which has been helpful, and there are opportunities for patients to obtain grants from certain foundations to help cover those out-of-pocket costs.

"We use a website called FundFinder to identify grants that patients may be eligible for," reports Ms. Mote. FundFinder tracks charitable patient assistance foundations and provides information in a central location when foundations have funds available that patients with a specific disease can apply for. "The grant programs ask for information about income and taxes so we make sure we get that information from patients so that we have it available to apply when grants become available," Ms. Mote explains. The website for the organization is https://fundfinder.

panfoundation.org/.

We also refer to patient assistance programs offered through manufacturers if grant coverage is not available, notes Ms. Mote. "There isn't a single patient in the past year that we haven't been able to treat with an ARPI due to financial reasons," she observes.

Medicare beneficiaries who are enrolled in the APC clinic are enrolled in the Medicare Chronic Care Management program, which provides reimbursement for ongoing patient care including phone calls. This program helps to support the financial viability of the APC clinic's efforts. (The Centers for Medicare and Medicaid Services provides information about Chronic Care Management eligibility and billing at https://www.cms.gov/files/document/chroniccaremanagement.pdf)

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