Genitourinary Masterclass

Workshops

Care for patients with advanced prostate cancer: Adding life to years

Bone health

Professor Ugo De Giorgi

Professor Vincent Khoo

Prescribing information is available at the end of this presentation.
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Xtandi™ enzalutamide

astellas

MAT-NL-XTD-2025-00038 | July 2025

XTANDI™ (enzalutamide) indications

XTANDI is indicated, as per the EMA SmPC:

- As monotherapy or in combination with ADT for the treatment of adult men with high-risk biochemical recurrent non-metastatic HSPC who are unsuitable for salvage radiotherapy
- In combination with ADT for the treatment of adult men with mHSPC
- For the treatment of adult men with high-risk non-metastatic CRPC
- For the treatment of adult men with mCRPC who are asymptomatic or mildly symptomatic after failure of ADT and in whom chemotherapy is not yet clinically indicated
- For the treatment of adult men with mCRPC whose disease has progressed on or after docetaxel therapy

XTANDI is subject to medicinal prescription.
Astellas Pharma B.V., Sylviusweg 62, 2333 BE Leiden, The Netherlands.
ADT, androgen deprivation therapy; EMA, European Medicines Agency; CRPC, castration-resistant prostate cancer; HSPC, hormone-sensitive prostate cancer; mCRPC, metastatic castration-resistant prostate cancer; mHSPC, metastatic hormone-sensitive prostate cancer; SmPC, Summary of Product Characteristics.
XTANDI (enzalutamide). Summary of Product Characteristics.
MAT-NL-XTD-2025-00038 | July 2025.

Genitourinary Masterclass

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The importance of bone health in advanced prostate cancer

Professor Ugo De Giorgi

University of Salento, Lecce - Italy

MAT-NL-XTD-2025-00038 | July 2025

Disclosures

The speaker has received an honorarium from Astellas for this presentation

Consultant/advisory board member:

- Astellas, AstraZeneca, Bayer, Bristol Myers Squibb, Ipsen, Janssen, Merck, MSD, Novartis, PharmaMar, Pfizer, Roche

Travel support:

- AstraZeneca, Bristol Myers Squibb, Ipsen, Janssen and Pfizer

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- AstraZeneca, Roche and Sanofi (paid to institution)

The importance of bone health in prostate cancer

European Journal of Cancer 218 (2025) 115293

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journal homepage: www.ejcancer.com

Assessment of bone mineral density in men with de novo metastatic castration-sensitive prostate cancer treated with or without abiraterone acetate plus prednisone in the PEACE-1 phase 3 trial

Guilhem Roubaud[a,*], Marie Kostine[b], Raymond S. McDermott[c], Alice Bernard-Tessier[d], Xavier Maldonado[e], Marlon Silva[f], Aude Fléchon[g], Dominik R. Berthold[h], Philippe Ronchin[i], Bertrand F. Tombal[j], Loïc Mourey[k], Gwenaëlle Gravis[l], Anne Escande[m], Sophie Abadie-Lacourtoisie[n], Tristan Maurina[o], Miguel A. Climent[p], Hélène Ribault[q], Alberto Bossi[d], Stéphanie Foulon[r,s], Karim Fizazi[d]

Evolution of mean percent changes in BMD over the first 2 years in lumbar spine

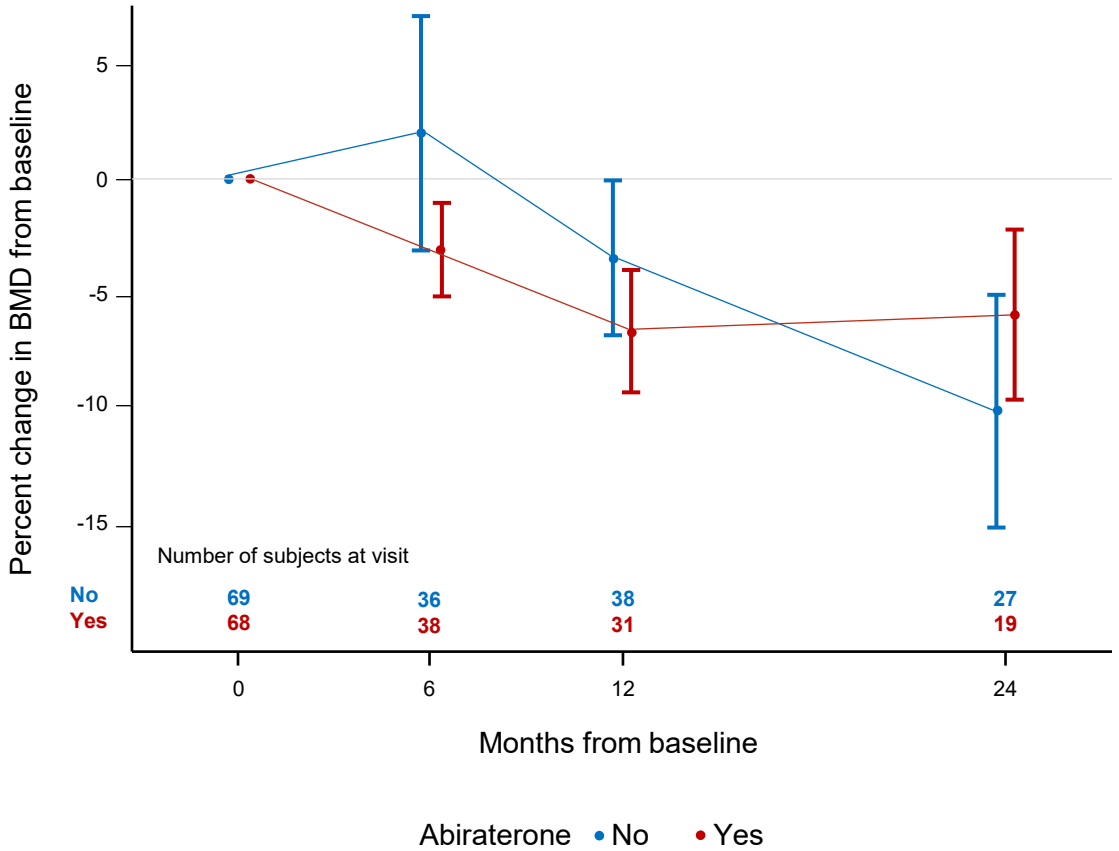


Figure adapted from Boubaud G et al., 2025.
BMD, bone mineral density.
Roubaud G et al. *Eur J Cancer* 2025;218:115293.
MAT-NL-XTD-2025-00038 | July 2025

The importance of bone health in advanced prostate cancer

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 AUGUST 20, 2009 VOL. 361 NO. 8

Denosumab in Men Receiving Androgen-Deprivation Therapy for Prostate Cancer

Matthew R. Smith, M.D., Ph.D., Blair Egerdie, M.D., Narciso Hernández Toriz, M.D., Robert Feldman, M.D., Teuvo L.J. Tammela, M.D., Fred Saad, M.D., Jiri Heracek, M.D., Ph.D., Maciej Szwedowski, M.D., Chunlei Ke, Ph.D., Amy Kupic, M.A., Benjamin Z. Leder, M.D., and Carsten Goessl, M.D.,

RESULTS

At 24 months, bone mineral density of the lumbar spine had increased by 5.6% in the denosumab group as compared with a loss of 1.0% in the placebo group (P<0.001); significant differences between the two groups were seen at as early as 1 month and sustained through 36 months. Denosumab therapy was also associated with significant increases in bone mineral density at the total hip, femoral neck, and distal third of the radius at all time points. Patients who received denosumab had a decreased incidence of new vertebral fractures at 36 months (1.5%, vs. 3.9% with placebo) (relative risk, 0.38; 95% confidence interval, 0.19 to 0.78; P=0.006). Rates of adverse events were similar between the two groups.

CONCLUSIONS

Denosumab was associated with increased bone mineral density at all sites and a reduction in the incidence of new vertebral fractures among men receiving androgen-deprivation therapy for nonmetastatic prostate cancer. (ClinicalTrials.gov number, NCT00089674.)

Cumulative Incidence of New Vertebral Fracture at 12, 24, and 36 Months, According to Study Group.

The relative risk for vertebral fracture among 679 patients in the denosumab group as compared with 673 patients in the placebo group was 0.15 at 12 months, 0.31 at 24 months, and 0.38 at 36 months.

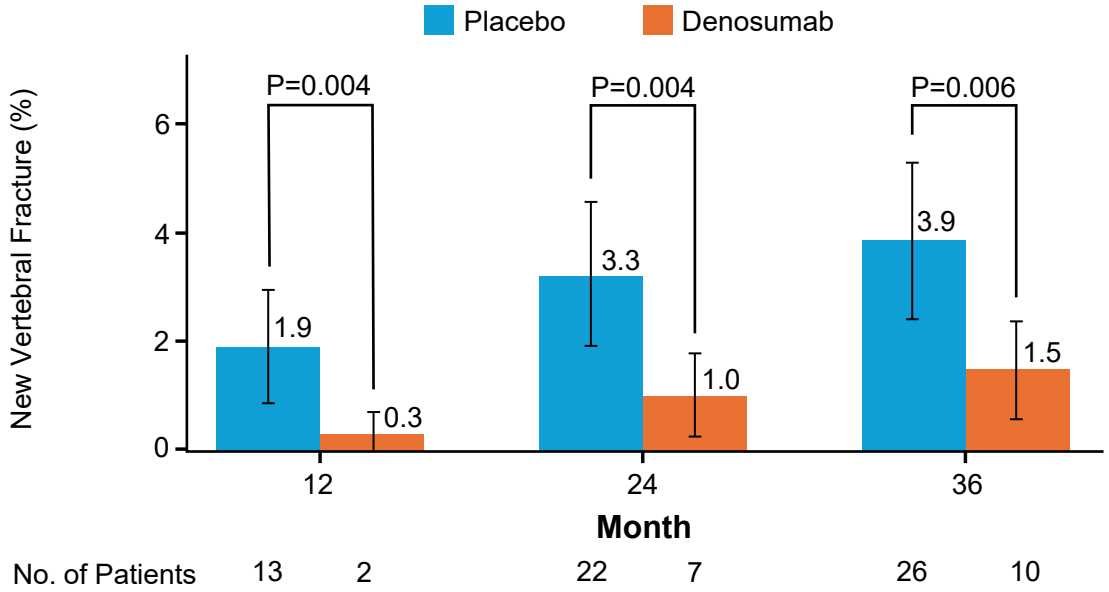


Figure adapted from Smith MR, et al., 2009.
Smith MR, et al. *New Engl J Med* 2009;361:745–755.

The importance of bone health in advanced prostate cancer

ORIGINAL ARTICLE

Metabolic, cardiac, and bone health testing in patients with prostate cancer on androgen-deprivation therapy: A population-based assessment of adherence to therapeutic monitoring guidelines

Ahmad Mousa MD[1] | David-Dan Nguyen MDCM, MPH[1] | Aly-Khan Lalani MD[2] |

Results: In total, 29,097 patients were examined, of whom 52.8% were prescribed ADT by urologists, 37.9% were prescribed ADT by radiation oncologists, 2.8% were prescribed ADT by medical oncologists, and 2.4% were prescribed ADT by other physicians. Adherence to guidelines was low: only 21.3% of patients received a bone density scan, 41.2% underwent bone health–related serum tests, 51.3% completed a lipid profile, and 65.9% underwent dysglycemia testing within 1 year of diagnosis. Overall, only 11.9% of patients received all of the recommended investigations. Adherence to testing did not appear to improve over time (2008–2021) or with guideline publication. Patient (age) and physician (specialty) factors had important associations with adherence to testing.

Conclusions: Most patients receiving ADT for prostate cancer do not receive recommended testing to monitor for treatment-related toxicity. Further study is required to address barriers to therapeutic monitoring of men on ADT and to reduce treatment-associated adverse events.

Low adherence of specialists in prescribing bone health evaluations

Frequency of test outcomes among individuals who remained alive 1 year after ADT prescription by therapy duration

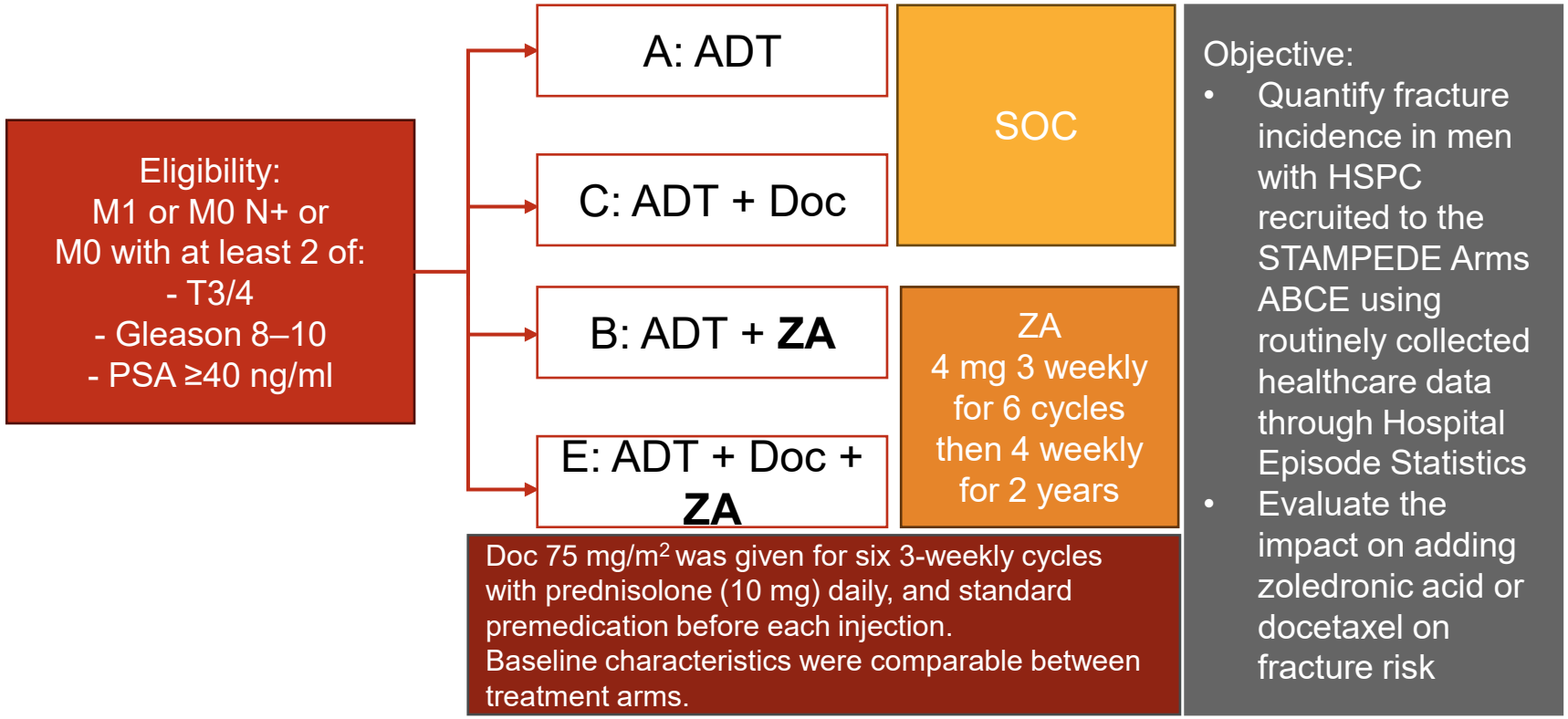
Variable, n (%)	≤12 months of ADT (n=6709)	13–36 months of ADT (n=11,597)	>36 months of ADT (n=8078)	Total (N=26,381)	p
Bone health within 1 year*	2010 (30.0)	5218 (45.0)	3651 (45.2)	10,879 (41.2)	<0.001
DEXA scan within 1 year	826 (12.3)	2761 (23.8)	2021 (25.0)	5608 (21.3)	<0.001
Lipid profile within 1 year	3114 (46.4)	6025 (52.0)	4402 (54.5)	13,541 (51.3)	<0.001
Dysglycaemia testing within 1 year	3950 (58.9)	78466 (67.7)	5581 (69.1)	17,377 (65.9)	<0.001
All tests received within 1 year	441 (6.6)	1526 (13.2)	1177 (14.6)	3144 (11.9)	<0.001

Tests received within 1 year of first ADT prescription based on the year of first ADT prescription

ADT year	Dysglycaemia	Lipid profile	Bone health serum tests	DEXA scan
2008–2010	2697 (67.7)	2048 (51.4)	1603 (40.3)	860 (21.6)
20011–2013	3633 (65.4)	2755 (49.6)	2119 (38.1)	1122 (20.2)
2014–2016	4468 (67.3)	3439 (51.8)	2872 (43.3)	1468 (22.1)
2017–2019	5697 (66.6)	4387 (51.3)	3720 (43.5)	1760 (20.6)
2019–2021	2233 (51.2)	1540 (35.3)	1524 (35.0)	601 (13.8)
Cohran–Armitage trend test	*p*<0.0001	*p*<0.0001	*p=0.4176*	*p<0.0001*

Tables adapted from Mousa A, et al., 2025.
*Test outcomes are defined from 6 weeks before to 1 year after the date of first ADT prescription.
ADT, androgen-deprivation therapy; DEXA, dual x-ray absorptiometry scan.
Mousa A, et al. *Cancer* 2025;131:e35606.

Fracture risk in prostate cancer: Insights from STAMPEDE



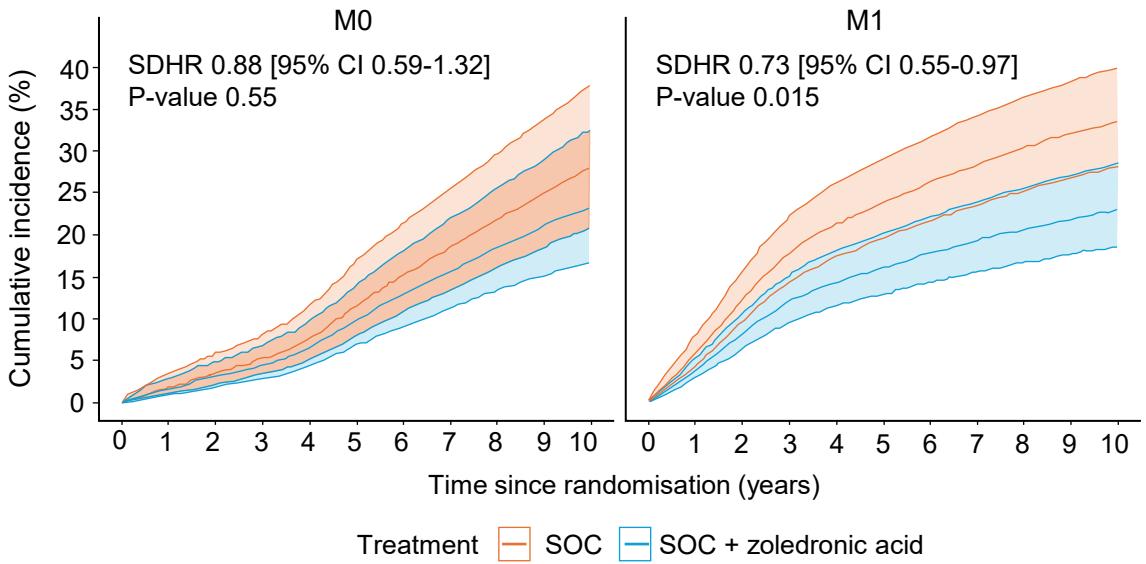
ADT, androgen deprivation therapy; CI, confidence interval; Doc, docetaxel; FRH, fracture-related hospitalisation; M, metastasis; N, node; PSA, prostate-specific antigen; SDHR, subdistribution hazard ratio; SOC, standard of care; T, tumour; ZA, zoledronic acid.

1. Jones C, et al. Presented at ESMO 2023, 20–24 October 2023, Madrid, Spain. Abstract 1768MO; 2. Klaassen Z. UroToday.com. Available at: https://www.urotoday.com/conference-highlights/esmo-2023/esmo-2023-prostate-cancer/147525-esmo-2023-healthcare-data-from-the-stampede-docetaxel-and-zoledronic-acid-comparisons-incidence-of-fracture-related-hospitalisations-in-men-with-de-novo-high-risk-and-mhspc.html. Last accessed July 2025.

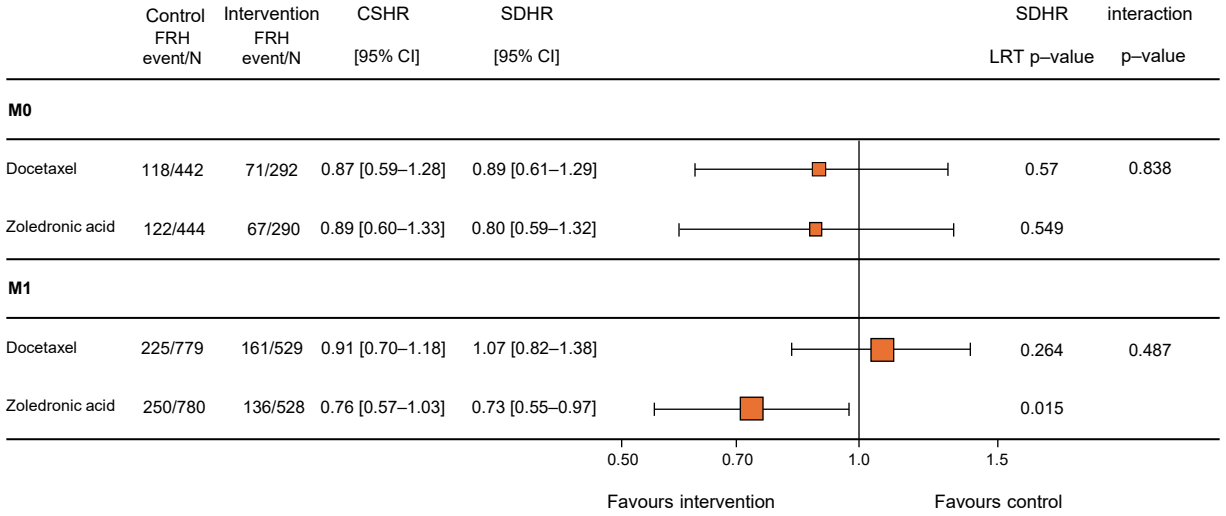
Fracture risk in prostate cancer: Insights from STAMPEDE

- **The 5-year** cumulative incidence rates of **FRH** in patients treated with **ADT** for **M1 and M0 were 23%** (95% CI: 19–28) and **11%** (95% CI: 8–15), respectively
- The 10-year cumulative incidence rate with ADT in patients with M0 disease was 26% (95% CI: 20–33)

Impact of ZA on 10-year incidence of fracture-related hospitalisations in patients with M0 or M1 disease



The effect of DOC or ZA on fracture related hospitalisations in patients with M1 or M0 disease



- **Docetaxel** had **no significant effect on FRH** in patients with M1 (p=0.264) and M0 (p=0.570) disease, and there was **no evidence of interaction between zoledronic acid and docetaxel** in patients with either M1 or M0 disease
- **Among patients receiving zoledronic acid, the incidence of FRH was statistically significantly reduced only in patients with M1 disease** (HR 0.73; p=0.015); data were inconclusive in patients with M0 disease (HR 0.88; p=0.55)

Figures adapted from Klaassen Z., 2023.[2]

ADT, androgen deprivation therapy; CI, confidence interval; Doc, docetaxel; FRH, fracture-related hospitalisation; HSPC, hormone-sensitive prostate cancer; HR, hazard ratio; LRT, likelihood ratio test; M, metastasis; N, node; PSA, prostate-specific antigen; SDHR, subdistribution hazard ratio; SOC, standard of care; T, tumour; ZA, zoledronic acid.

1. Jones C, et al. Presented at ESMO 2023, 20–24 October 2023, Madrid, Spain. Abstract 1768MO; 2. Klaassen Z. UroToday.com. Available at: https://www.urotoday.com/conference-highlights/esmo-2023/esmo-2023-prostate-cancer/147525-esmo-2023-healthcare-data-from-the-stampede-docetaxel-and-zoledronic-acid-comparisons-incidence-of-fracture-related-hospitalisations-in-men-with-de-novo-high-risk-and-mhspc.html. Last accessed July 2025.

Bone health in mHSPC

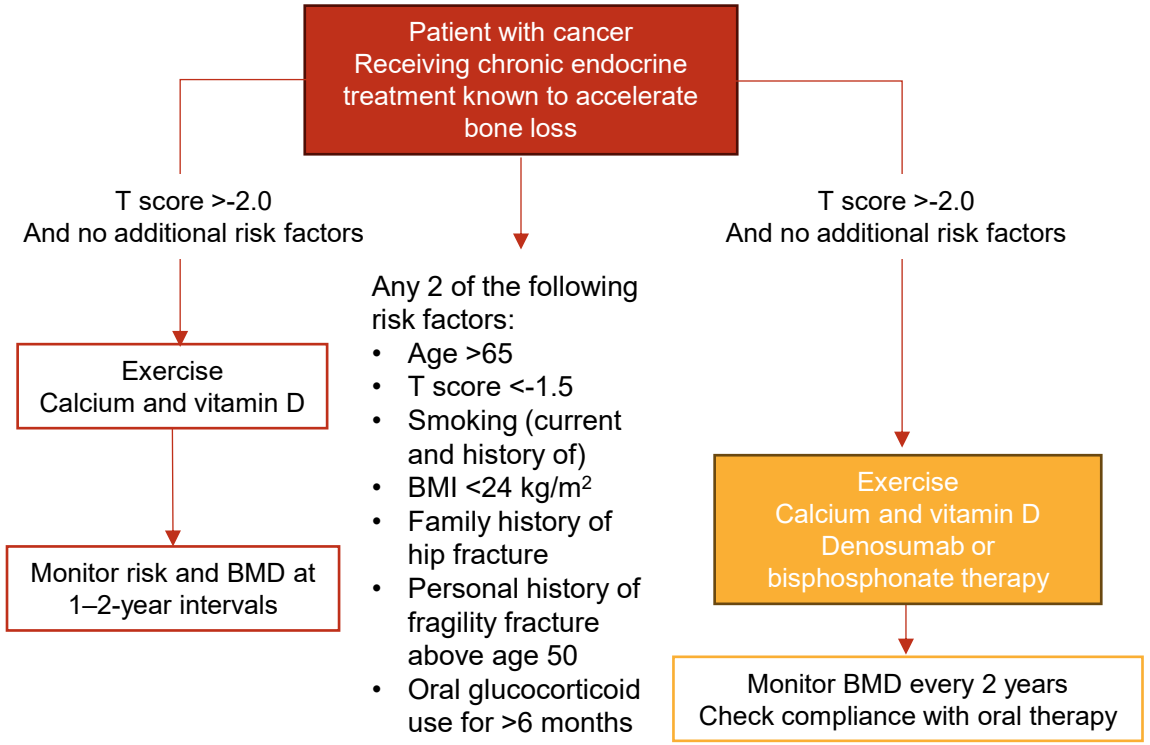
ESMO GOOD SCIENCE BETTER MEDICINE BEST PRACTICE

ANNALS OF ONCOLOGY driving innovation in oncology

SPECIAL ARTICLE 1

Bone health in cancer: ESMO Clinical Practice Guidelines†

R. Coleman[1], P. Hadji[2,3], J.-J. Body[4], D. Santini[5], E. Chow[6], E. Terpos[7], S. Oudard[8], Ø. Bruland[9,10], P. Flamen[11], A. Kurth[12,13], C. Van Poznak[14], M. Aapro[15] & K. Jordan[16], on behalf of the ESMO Guidelines Committee*



ESMO GOOD SCIENCE BETTER MEDICINE BEST PRACTICE

ESMO OPEN SCIENCE FOR OPTIMAL CANCER CARE

ORIGINAL RESEARCH 2

Bone health and body composition in prostate cancer: Meet-URO and AIOM consensus about prevention and management strategies

M. C. Cursano[1†], A. A. Valsecchi[2†], F. Pantano[3], M. Di Maio[2], G. Procopio[4], A. Berruti[5], F. Bertoldo[6], M. Tucci[7], U. De Giorgi[1†] & D. Santini[8*†], on behalf of the Meet-URO and AIOM experts[§]

Italian consensus conference:

- A BTA should be administered at the beginning of ADT according to the schedule and dosage for the prevention of CTIBL
- In principle, a BTA should not be administered with the same dosage used for the prevention of metastatic bone SREs, although individual cases should be evaluated
- In mHSPC:
  - Denosumab 60 mg every 6 months or bisphosphonates (alendronate, risedronate, zoledronate) with supplementary vitamin D and calcium
- Treatment should be continued until CRPC and then should be followed according to mCPRC indications[2]

Figure adapted from Coleman R, et al., 2020.[1]
ADT, androgen deprivation therapy; BMD, bone mineral density; BTA, bone targeting agent; CTIBL, cancer treatment induced bone loss; (m)CRPC, (metastatic) castration-resistant prostate cancer; mHSPC, metastatic hormone-sensitive prostate cancer; SRE, skeletal-related events.
1. Coleman R, et al. *Ann Oncol* 2020;13:1650–1663; 2. Cursano M.C, et al. *ESMO Open* 2024;9:103484.

Genitourinary Masterclass

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The importance of bone health: **Case study**

Professor Vincent Khoo

The Royal Marsden, London, United Kingdom

MAT-NL-XTD-2025-00038 | July 2025

Disclosures

Prof Khoo has received honoraria for advisories, consultancies, speaker forums and conferences from the following companies:

- Accuray
- Advanced Accelerators Applications
- Astellas
- Astra Zeneca
- Bayer
- Bristol Myers Squibb
- Boston Scientific
- Janssen
- Merck Serono
- Merck Sharp & Dohme
- Novartis

Presenting Mr A Prostate

Today we'll talk about:

- The case: What happened
- Learnings: What could have been done better for Mr A Prostate
- Best practice for preserving bone health for patients with mHSPC

Image freely available from Microsoft PowerPoint.
mHSPC, metastatic hormone-sensitive prostate cancer.
MAT-NL-XTD-2025-00038 | July 2025

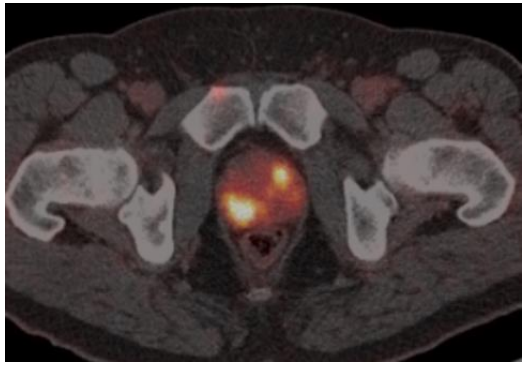
Case mHSPC: Mr A Prostate

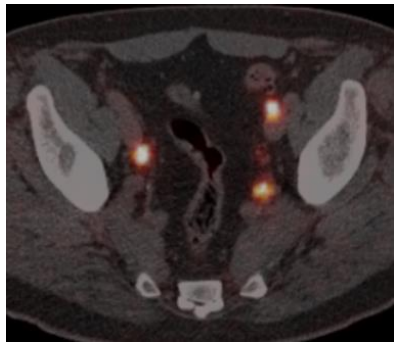
66 y.o. retired teacher

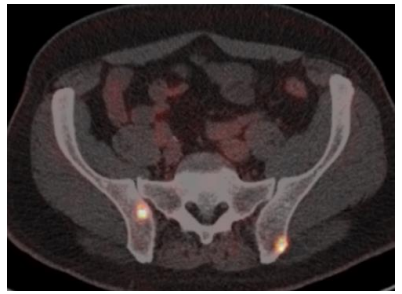
- PMH: Type 2 diabetes, HT
- Medicines: Metformin, lisinopril, atorvastatin
- Married: 3 children, 1 grand-child. Hobby train enthusiast
- PW: LUTS, ECOG 1
- GP: PSA 11 ng/mL (5-2018)
- Prostate biopsy: Gl 5+4

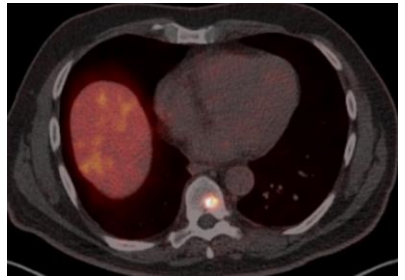
Diagnosis

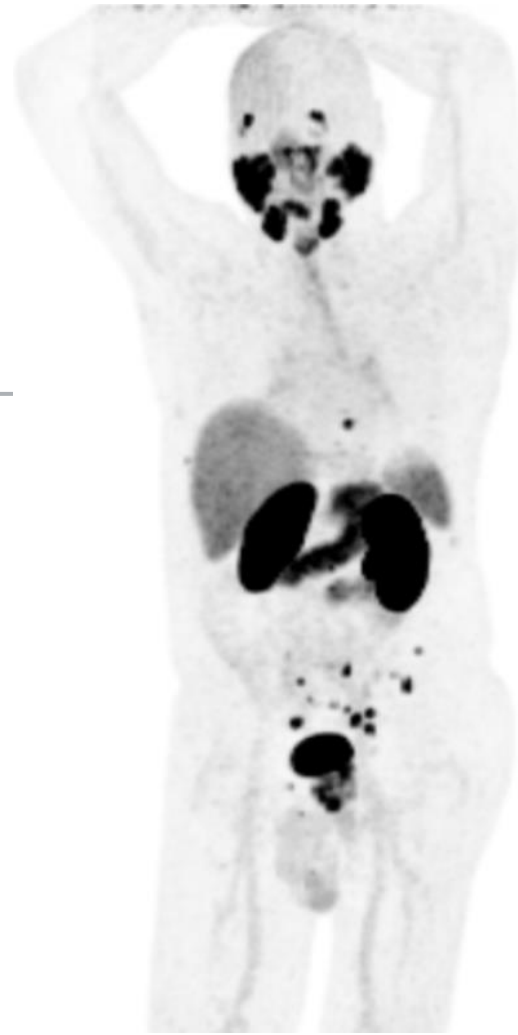
6-2018: MRI, PSMA
T3B N1 M1











ECOG, Eastern Cooperative Oncology Group; GI, Gleason index; GP, general practitioner; HT, hypertension; LUTS, lower urinary tract symptoms; mHSPC, metastatic hormone-sensitive prostate cancer; MRI, magnetic resonance imaging; PMH, past medical history; PSA, prostate-specific antigen; PSMA, prostate-specific membrane antigen; PW, presents with.
Clinical case and images provided by the speaker with consent.
MAT-NL-XTD-2025-00038 | July 2025

Case mHSPC: Mr A Prostate

What would you have done next?

BMI 30 kg/m^2, HbA1c 42 mmol/mol, BP 140/90 mmHg, Total cholesterol 6.1 mmol/l

- More investigations
- Assess co-morbidities
- Optimised health indices
- Proceed to treatment ASAP

BMI, body mass index; BP, blood pressure; HbA1c, glycated haemoglobin; mHSPC, metastatic hormone-sensitive prostate cancer.

Case mHSPC: Mr A Prostate

66 y.o. retired teacher

- PMH: Type 2 diabetes, HT
- Medicines: Metformin, lisinopril, atorvastatin
- Married: 3 children, 1 grand-child. Hobby train enthusiast
- PW: LUTS, ECOG 1
- GP: PSA 11 ng/mL (5-2018)
- Prostate biopsy: Gl 5+4

Diagnosis

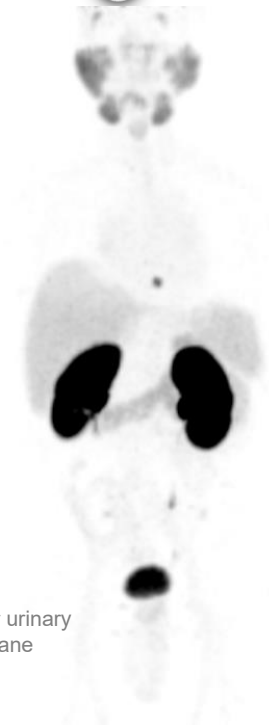
6-2018: MRI, PSMA PET
T3B N1 M1

Treatment

07-2018: Bicalutamide then ADT
10-2018: Docetaxel x6
Colour Genomics (30gp): neg
03-2019: IMRT prostate + pelvis

Assessment

05-2018 PSMA good response
SBRT T8



ADT, androgen deprivation therapy; ECOG, Eastern Cooperative Oncology Group; GI, Gleason index; GP, general practitioner; HT, hypertension; IMRT, intensity modulated radiotherapy; LUTS, lower urinary tract symptoms; mHSPC, metastatic hormone-sensitive prostate cancer; MRI, magnetic resonance imaging; PMH, past medical history; PSA, prostate-specific antigen; PSMA, prostate-specific membrane antigen; PW, presents with.

Clinical case and images provided by the speaker with consent.

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- GP: PSA 11 ng/mL (5-2018)
- Prostate biopsy: Gl 5+4

Diagnosis

6-2018: MRI, PSMA PET
T3B N1 M1

Assessment

05-2022: PSA nadir 0.5 ng/ml
11-2022: PSA 1.91 ng/ml

05-2022: T 0.4
12-2022: T 1.5

Treatment

07-2018: Bicalutamide then ADT
10-2018: Docetaxel x6
Colour Genomics (30gp): neg
03-2019: IMRT prostate + pelvis
05-2019: SBRT T8

ADT, androgen deprivation therapy; ECOG, Eastern Cooperative Oncology Group; GI, Gleason index; GnRH, gonadotropin releasing hormone; GP, general practitioner; HT, hypertension; IMRT, intensity modulated radiotherapy; LUTS, lower urinary tract symptoms; mHSPC, metastatic hormone-sensitive prostate cancer; MRI, magnetic resonance imaging; PMH, past medical history; PSA, prostate-specific antigen; PSMA PET, prostate-specific membrane antigen positron emission tomography; PW, presents with; SBRT, stereotactic body radiotherapy.
Clinical case provided by the speaker.
MAT-NL-XTD-2025-00038 | July 2025

Case mHSPC: Mr A Prostate

What would you have done next?

Patient asymptomatic apart from lethargy, not anxious

- Exclude UTI
- Monitor until PSA higher
- Monitor clinically until symptoms
- Investigate now

mHSPC, metastatic hormone-sensitive prostate cancer; PSA, prostate-specific antigen; UTI, urinary tract infection.

Case mHSPC: Mr A Prostate

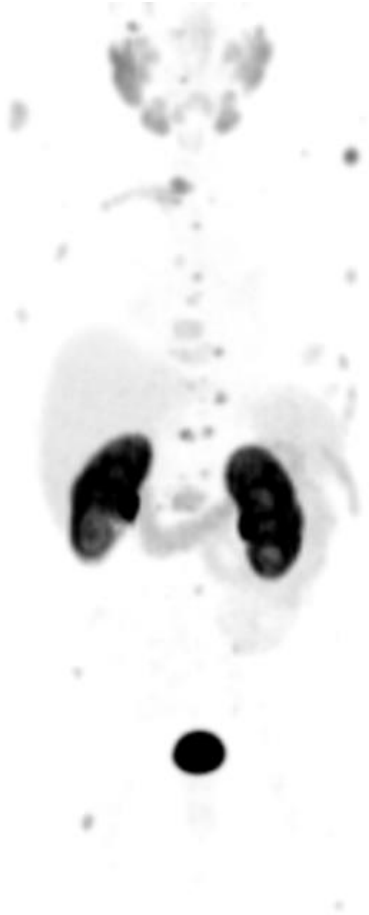
71 y.o. retired teacher

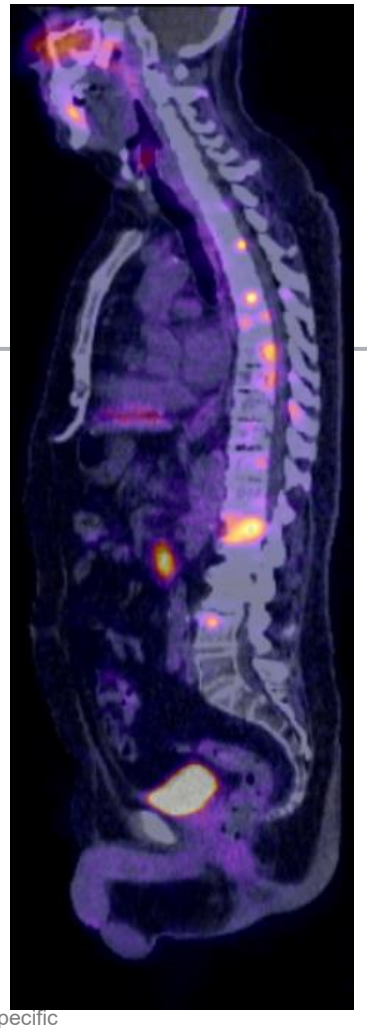
- 2018: PSA 11 ng/ml, GI 5+4, T3B N1 M1
- 2018-2019: ADT, Docetaxel, RT pelvis, SBRT T8
- 11-2022: PSA 1.91 ng/ml
- 02-2023: PSA 2.5 ng/ml

Assessment

02-2023: Repeat PSMA PET

PSMA PET: new widespread avid metastases in the axial and appendicular skeleton, almost occult on the accompanying CT component





ADT, androgen deprivation therapy; CT, computed tomography; GI, Gleason index; mHSPC, metastatic hormone-sensitive prostate cancer; PSA, prostate-specific antigen; PSMA PET, prostate-specific membrane antigen positron emission tomography; RT, radiotherapy; SBRT, stereotactic body radiotherapy.
Clinical case and images provided by the speaker with consent.
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Case mHSPC: Mr A Prostate

71 y.o. retired teacher

- 2018: PSA 11 ng/ml, GI 5+4, T3B N1 M1
- 2018-2019: ADT, Docetaxel, RT pelvis, SBRT T8
- 11-2022: PSA 1.91 ng/ml
- 02-2023: PSA 2.5 ng/ml,

  T 3.1

Assessment

02-2023: PSMA PET; PD widespread bone mets

Treatment

03-2023: Restart ADT & Enzalutamide. (Patient outlined letter to GP to start alendronate* was not initiated at first ADT)
09-2023: PSA nadir 0.25 ng/ml

Assessment

06-2024: PSA 1.84 ng/ml

Restage: New bone mets & symptomatic

*Note: Alendronate is not approved for use in prostate cancer.
ADT, androgen deprivation therapy; CT, computed tomography; GI, Gleason index; GP, general practitioner; mHSPC, metastatic hormone-sensitive prostate cancer; PD, progressive disease; PSA, prostate-specific antigen; PSMA PET, prostate-specific membrane antigen positron emission tomography; RT, radiotherapy; SBRT, stereotactic body radiotherapy.
Clinical case and images provided by the speaker with consent.
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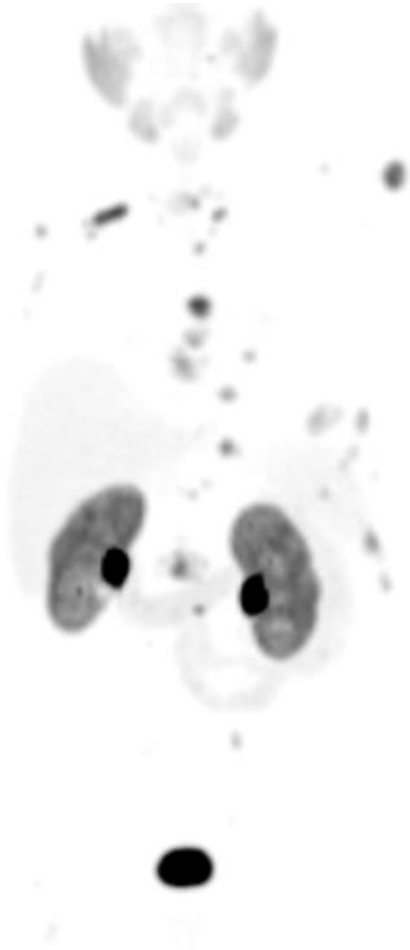
- 2018-2019: ADT, Docetaxel, RT pelvis, SBRT T8
- 11-2022: PSA 1.91 ng/ml
- 02-2023: PSA 2.5 ng/ml,

T 3.1

Assessment

02-2023: PSMA PET; F
widespread bone mets



03-2
Enz
outli
alen ed
at fi
09-2 g/ml

Assessment

06-2024: PSA 1.84 ng/ml

Restage: New bone mets & symptomatic

*Note: Alendronate is not approved for use in prostate cancer.
ADT, androgen deprivation therapy; CT, computed tomography; GI, Gleason index; GP, general practitioner; mHSPC, metastatic hormone-sensitive prostate cancer; PD, progressive disease; PSA, prostate-specific antigen; PSMA PET, prostate-specific membrane antigen positron emission tomography; RT, radiotherapy; SBRT, stereotactic body radiotherapy.
Clinical case and images provided by the speaker with consent.
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Case mHSPC: Mr A Prostate

What would you have done next?

Patient symptomatic bone pain (poorly localised), PS 1/2

- Zoledronic acid (if not used before)
- Rechallenge Docetaxel
- Clinical Trials

mHSPC, metastatic hormone-sensitive prostate cancer; PS, performance score.

Case mHSPC: Mr A Prostate

71 y.o. retired teacher

- 2018: PSA 11 ng/ml, GI 5+4, T3B N1 M1
- 2018-2019: ADT, Docetaxel, RT pelvis, SBRT T8
- 11-2022: PSA 1.91 ng/ml
- 02-2023: PSA 2.5 ng/ml

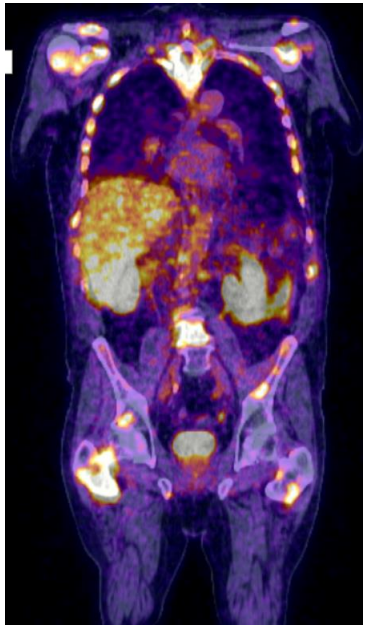
T 3.1

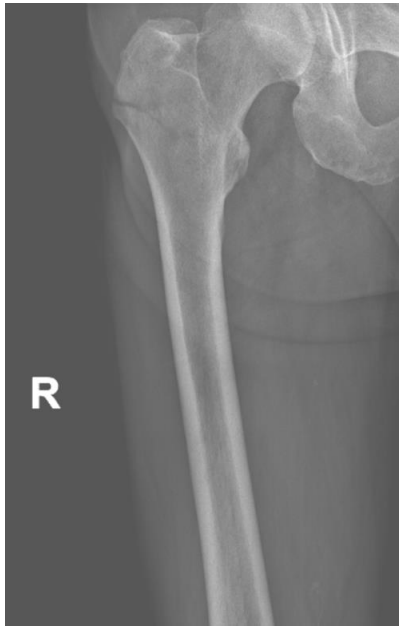
Assessment

03-2024: PSA 5.2 ng/ml, Bone pain, especially right hip pain

Treatment

07-2024: Ra-223 x6
12-2024: PSA 4.1 ng/ml





ADT, androgen deprivation therapy; GI, Gleason index; mHSPC, metastatic hormone-sensitive prostate cancer; PSA, prostate-specific antigen; RT, radiotherapy; SBRT, stereotactic body radiotherapy.
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Learnings: What could have been done better for Mr A Prostate

Consider co-morbidities

- Initiate early referrals to optimise and reduce co-morbidities

Consider bone health management

- e.g. Zoledronic acid

Double check on patient management if out-sourcing to GP

Consider patient preferences and holistic needs

GP, general practitioner.
Speaker's recommendations.

Best practice for preserving bone health for patients with mHSPC

Baseline assessment

- Past medical history and predisposing/ risk factors
- Review co-morbidities and medications
- Assess bone density

Monitoring throughout treatment

- Fracture risk assessments
  e.g. FRAX (Fracture Risk Assessment Tool)

Reactive management of bone health

Proactive management of bone health

- Patient education and lifestyle management
- Calcium and Vit D
- Bone protective agents

Speaker's recommendations.

Genitourinary Masterclass

astellas

Please refer to the EMA SmPC for XTANDI™ (enzalutamide) via the following link: https://www.ema.europa.eu/en/documents/product-information/xtandi-epar-product-information_en.pdf

Scan/click here for the XTANDI™ UK prescribing information

Scan/click here for the XTANDI™ NL SmPC

XTANDI™ is subject to medicinal prescription.
Astellas Pharma B.V., Sylviusweg 62, 2333 BE Leiden, The Netherlands.
aPI, abbreviated Prescribing Information; EMA, European Medicines Agency; SmPC, Summary of Product Characteristics.
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