



THE STATE OF TRT: FEELING THE IMPACT OF TRENDS IN PRACTICE AND PATIENT CARE

A panel discussion on a 2024 SERMO Survey of 303 HCPs

PRESENTED BY:



Adrian Sandra Dobs, MD, MHS

Division of Endocrinology, Diabetes and Metabolism,
The Johns Hopkins University School of Medicine
Baltimore, MD



Sandeep Dhindsa, MBBS

Chief, Division of Endocrinology and Metabolism,
Saint Louis University, SLUCare Academic Pavilion
St. Louis, MO

Please see last slide for Important Safety Information
including **BOXED WARNING** on increases in blood pressure.

Disclaimer

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This presentation is not part of the ENDO 2024 official educational programming as planned by the Endocrine Society Annual Meeting Steering Committee. This event is neither sponsored nor ENDO by the Endocrine Society.

Important Safety Information for JATENZO (testosterone Undecanoate)

Indication and Limitations of Use:

JATENZO® (testosterone undecanoate) capsules, CIII, is an androgen indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone:

- Primary hypogonadism (congenital or acquired)
- Hypogonadotropic hypogonadism (congenital or acquired)

Safety and efficacy of JATENZO in males less than 18 years old have not been established.

IMPORTANT SAFETY INFORMATION FOR JATENZO (testosterone undecanoate)

WARNING: INCREASES IN BLOOD PRESSURE

- **JATENZO can cause blood pressure (BP) increases that can increase the risk of major adverse cardiovascular events (MACE), including non-fatal myocardial infarction, non-fatal stroke and cardiovascular death.**
- **Before initiating JATENZO, consider the patient's baseline cardiovascular risk and ensure blood pressure is adequately controlled.**
- **Periodically monitor for and treat new-onset hypertension or exacerbations of pre-existing hypertension and re-evaluate whether the benefits of JATENZO outweigh its risks in patients who develop cardiovascular risk factors or cardiovascular disease on treatment.**
- **Due to this risk, use JATENZO only for the treatment of men with hypogonadal conditions associated with structural or genetic etiologies.**

CONTRAINDICATIONS

JATENZO is contraindicated in men with carcinoma of the breast or known or suspected carcinoma of the prostate, in women who are pregnant, in men with a known hypersensitivity to JATENZO or its ingredients, or in men with hypogonadal conditions that are not associated with structural or genetic etiologies.

WARNINGS AND PRECAUTIONS

Increase blood pressure and Major Adverse Cardiovascular Events. JATENZO can increase blood pressure, which can increase the risk of MACE, with greater risk in patients with established cardiovascular disease or risk factors for cardiovascular disease.

Increase in hematocrit and polycythemia. High red blood cell counts increase the risk of clots, strokes, and heart attacks.

Benign prostatic hyperplasia (BPH). Patients may see worsening signs and symptoms of BPH.

Prostate cancer. Patients treated with androgens may be at increased risk for prostate cancer.

Venous thromboembolic events (VTE). Deep vein thrombosis (DVT) and pulmonary embolism (PE) have been reported in patients using testosterone replacement products like JATENZO.

Abuse. Testosterone has been subject to abuse, typically at doses higher than recommended for the approved indication and in combination with other anabolic androgenic steroids. Testosterone abuse can lead to serious cardiovascular and psychiatric adverse reactions.

Suppression of spermatogenesis. Large doses of androgens, like JATENZO, can suppress spermatogenesis.

Hepatic adverse events. JATENZO is not known to cause liver adverse events; however, patients should be instructed to report any signs of hepatic dysfunction.

Retention of sodium and water.

Gynecomastia.

Sleep apnea. Testosterone may potentiate sleep apnea in some patients, especially those with risk factors such as obesity or chronic lung disease.

Changes in the serum lipid profile may require dose adjustment of lipid-lowering drugs or discontinuation of testosterone therapy.

Risk of hypercalcemia.

ADVERSE EVENTS

The most common adverse events of JATENZO (incidence $\geq 2\%$) are headache (5%), increased hematocrit (5%), hypertension (4%), decreased HDL (3%), and nausea (2%).

DRUG INTERACTIONS

JATENZO can cause changes in insulin sensitivity or glycemic control and changes in anticoagulant activity. Use of testosterone and corticosteroids concurrently may increase fluid retention. Use of prescription and nonprescription analgesic cold medications with JATENZO have been known to increase blood pressure.

Please visit JatenzoHCP.com full Prescribing Information, including BOXED WARNING on increases in blood pressure.

JATENZO®
(testosterone undecanoate)
Capsules 

Introducing The Presenters



Adrian Sandra Dobs,
MD, MHS

Dr. Adrian Dobs is presently an active clinical researcher in the field of Endocrinology gonadal function, particularly interested in new forms of male hormone replacement therapy and has published extensively in the area of hormonal changes with aging and chronic disease. Her clinical practice covers general Endocrinology, with a focus on sex hormone disorders in both men and women.

As Director of the Johns Hopkins Clinical Research Network, she oversees a multi-institutional consortium of hospitals in the mid-Atlantic states dedicated to facilitating clinical research through an academic-community hospital partnership.



Sandeep Dhindsa,
MBBS

Dr. Sandeep Dhindsa is an Endocrinology specialist who treats conditions that include diabetes, low testosterone, thyroid, pituitary and adrenal disorders. His primary area of research is in the field of hypogonadism and type 2 diabetes.

Dr. Dhindsa is a professor in the Department of Internal Medicine and serves as the director of the Division of Endocrinology, Diabetes and Metabolism at Saint Louis University School of Medicine.

He is a member of the American Diabetes Association and the Endocrine Society. A fellow of the American Association of Clinical Endocrinologists, Dr. Dhindsa was also a member of the Scientific Reproductive Committee of that organization.

THE STATE OF TRT: FEELING THE IMPACT OF TRENDS IN PRACTICE AND PATIENT CARE

A Panel Discussion on a 2024 SERMO Survey of 303 HCPs

Agenda

- ▶ SERMO survey overview and objectives
- ▶ Survey findings and implications to practice and patient care
- ▶ Addressing common physician beliefs on oral TRT
- ▶ Join the conversation

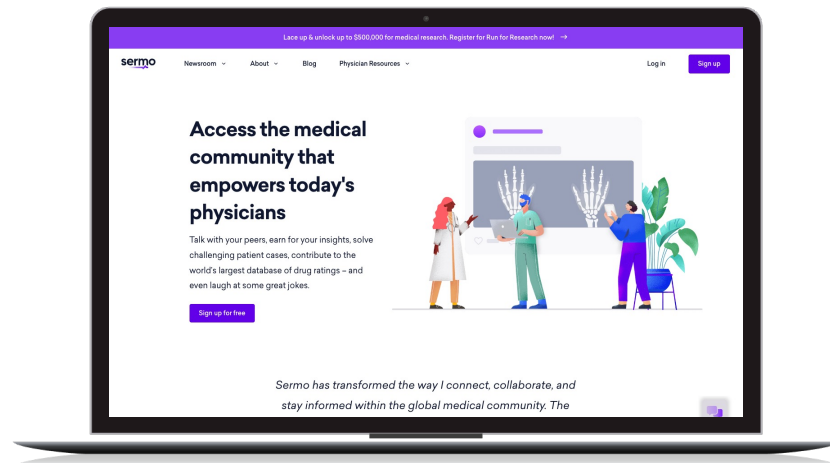
Use QR Code to
Submit Your Questions



First annual SERMO study of 303 TRT experienced physicians



‘Facebook for doctors’
World’s leading HCP
social network platform



Study Objectives

- Understand TRT patient experience and unmet needs
- Outline prescribing behaviors and barriers across multiple specialties
- Uncover myths and opportunities for patient and peer education

Base: Overall (n=303), Endocrinologists (n=100), Urologists (n=100), PCP+Others (n=103)
US physicians fielded in Feb 2024 by SERMO

Why we conducted this study

TRT is a fast-growing and rapidly changing category. Within the last year alone, we have seen:



Exit and/or sale of several formulations



Direct-from-manufacturer (cash) channel to reduce insurance hassle



A rise in small TRT clinics driving market development



Investment marketing for testosterone boosting supplements



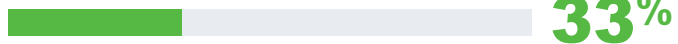
Evolving DTC business models

303 TRT experienced physicians¹

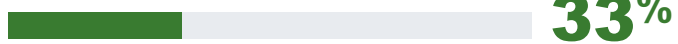
Specialty

(% of Physicians)

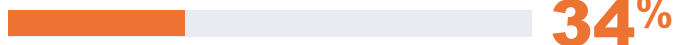
Endocrinologist



Urologist

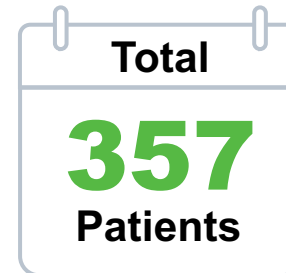


PCP & Other



Patients Seen in a Month

(Mean # of Patients)



Office Setting

(% Physicians)



71% General Office

21% Hospital/
System

6% TRT Focused
Clinic

3% Other

Time Spent in Professional Activities

(% of Physicians)

3%

Teaching

4%

Administration

94%

Patient care

Compounded Testosterone Rx Usage

(% of Physicians)

23%

TRT Experienced Physicians

(Average TRT Rx per year)

750
Total

907
Endos

HIGH LEVEL FINDINGS AND IMPLICATIONS TO PRACTICE AND PATIENT CARE



Scan the QR code for a
copy of the presentation

Understanding current TRT dialogue on oral therapies



Both physicians and patients are unaware of availability of oral TRTs¹

Physicians Say

Only 4% of endocrinologists can recall any branded oral TRT and majority of physicians (52%) don't include patient in final Rx decision

Implication:

Endocrinologists are driving decisions with low awareness of Oral TRT

Awareness

Patient Needs

Only 22% of TRT patients are aware of oral options

Implication:

Patients aren't always the final decision maker in their treatment; may not be aware of all options



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Reference: 1. Data on file. The Landmark SERMO survey: The state of TRT in 2024. (conducted February 16-March 1, 2024). Tolmar, Inc.

Physicians use safety concerns around liver toxicity & cardiovascular issues as a reason to avoid prescribing oral TRTs¹

Physicians Say

Over 50% of HCPs require more safety data before prescribing oral TRTs, citing toxicity concerns as major barrier (42%).

Implication:

Some Endocrinologists are not up-to-date: concerns over liver toxicity still very common, and half think TRT formulations differ in safety

Safety

Patient Needs

73% of patients have common myths around TRT and have lots of questions

Implication:

Patient's need education on TRT options

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Insurance hassles are #1 barrier to prescribing orals¹

Physicians Say

78% of endocrinologists write generics because they are easier to prescribe, and 23% of all HCPs use compounded testosterone

Implication:

If insurance is not a hassle, doctors are happy to switch between formulations

Access

Patient Needs

Physicians report 66% of patients switch TRT in a year. 56% of switches were due to patient's request

Implication:

Substantial amount of patient switching occurs to get a therapy that works for them



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Formulation choice may matter more than physicians think¹

Physicians Say

Less than half of injectable (41%) and gel (41%) patients have administration complaints

Implication:

“Injections and gels are easy”
HCPs may be de-sensitized to patient needs

Ease
of use

Patient Needs

Over a quarter of patients (26%) DO NOT TAKE their TRT as prescribed

Implication:

Patients are unable to get benefit from therapy if they don't take it.



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Utilization of oral TRT is low due to these three myths



Myth #1

I can't prescribe
orals due to
safety issues



Myth #2

Orals are not
worth the
insurance hassle
for physicians



Myth #3

Patients are
happy with
any TRT
I prescribe



Myth #1

I can't prescribe orals due to safety issues

Next-generation orals are not as safe as TRT options we've been comfortable using for years.

HCPs are not aware of branded oral TRT options¹

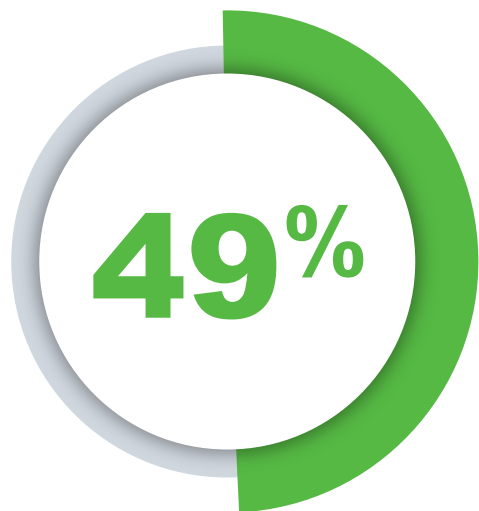
ONLY
4%

**of HCPs are aware of
branded oral TRT options**

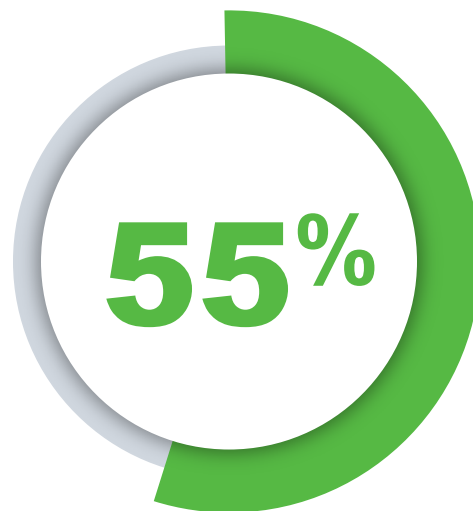
Top-of-mind unaided
awareness – TRT brands

- Many physicians have low awareness of, or lack clinical experience with, oral TRTs
- Physicians may not all be up -to-speed about market improvements

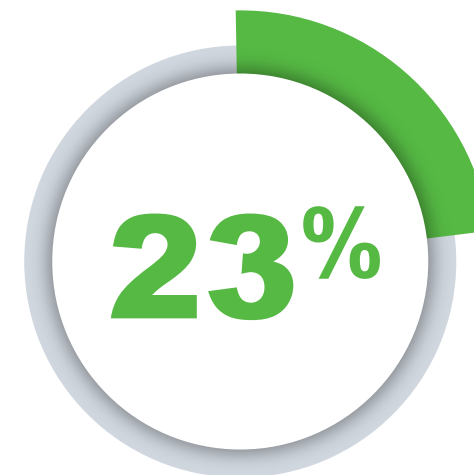
Even if aware of oral TRTs, physicians are not writing due to safety concerns¹



Other TRTs have a long track record and I prefer to stick with them



I require more safety data around oral TRTs before I would be comfortable prescribing them



There really isn't a difference between TRTs for safety

42% of endocrinologists surveyed cite concerns over liver toxicity as a barrier to prescribing an oral TRT¹

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JATENZO® Mode of absorption avoids first-pass hepatic metabolism¹⁻³

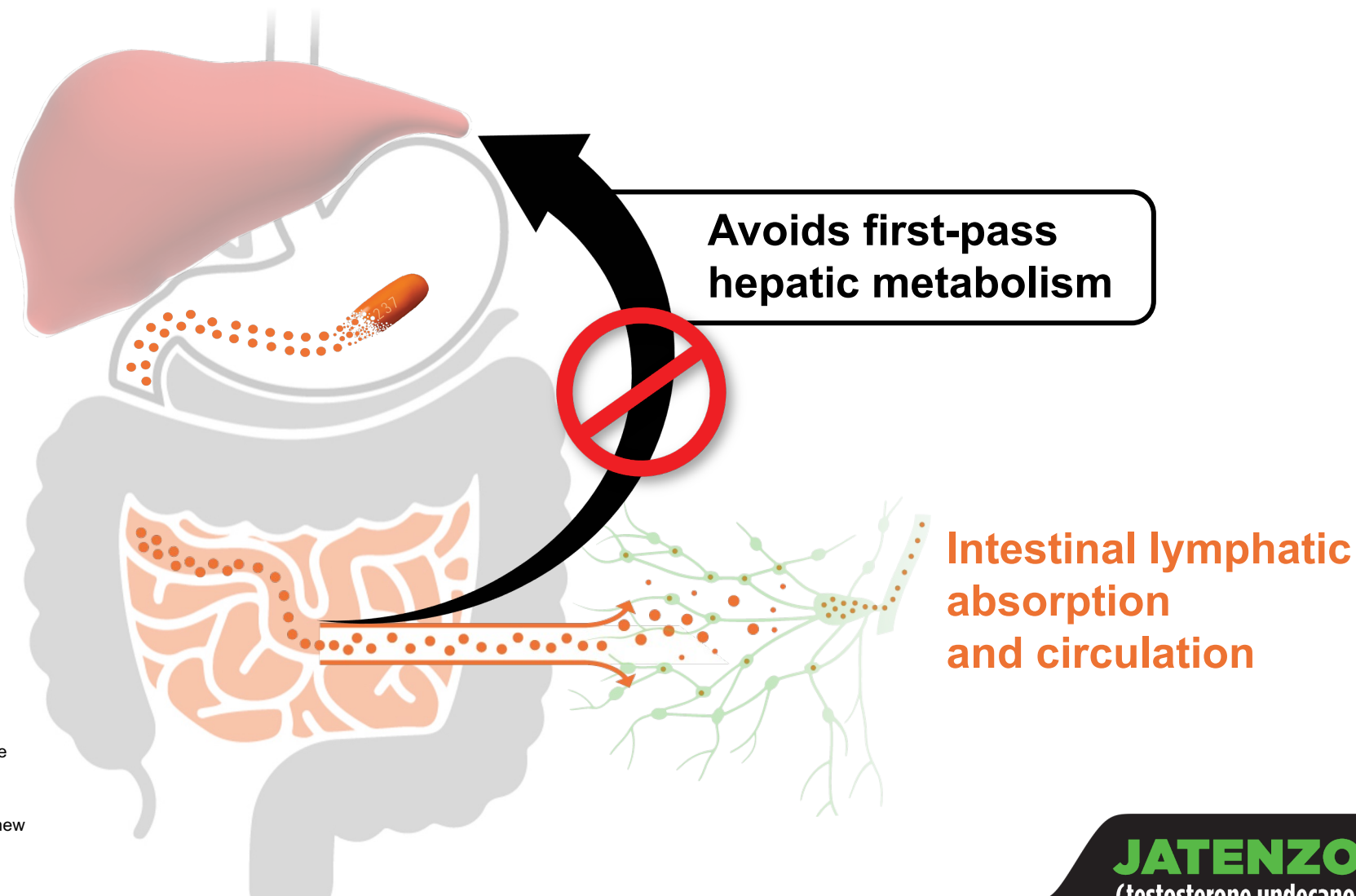
Important Safety Information (Continued)

CONTRAINDICATIONS

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Please see following slides for additional Important Safety Information. Visit JatenzoHCP.com for full Prescribing Information including **BOXED WARNING** on increases in blood pressure.

References: 1. JATENZO (testosterone undecanoate) capsules, for oral use CIII [package insert]. Fort Collins, CO: Tolmar, Inc.; 2023. 2. Swerdloff RS, Wang C, White WB, et al. A new oral testosterone undecanoate formulation restores testosterone to normal concentrations in hypogonadal men. *J Clin Endocrinol Metab.* 2020;105(8):2515-2531. 3. Swerdloff RS, Dudley RE. A new oral testosterone undecanoate therapy comes of age for the treatment of hypogonadal men. *Ther Adv Urol.* 2020;12:1-16.



JATENZO®
(testosterone undecanoate)
Capsules 

JATENZO offers safe, oral delivery¹⁻³

Important Safety Information (Continued)

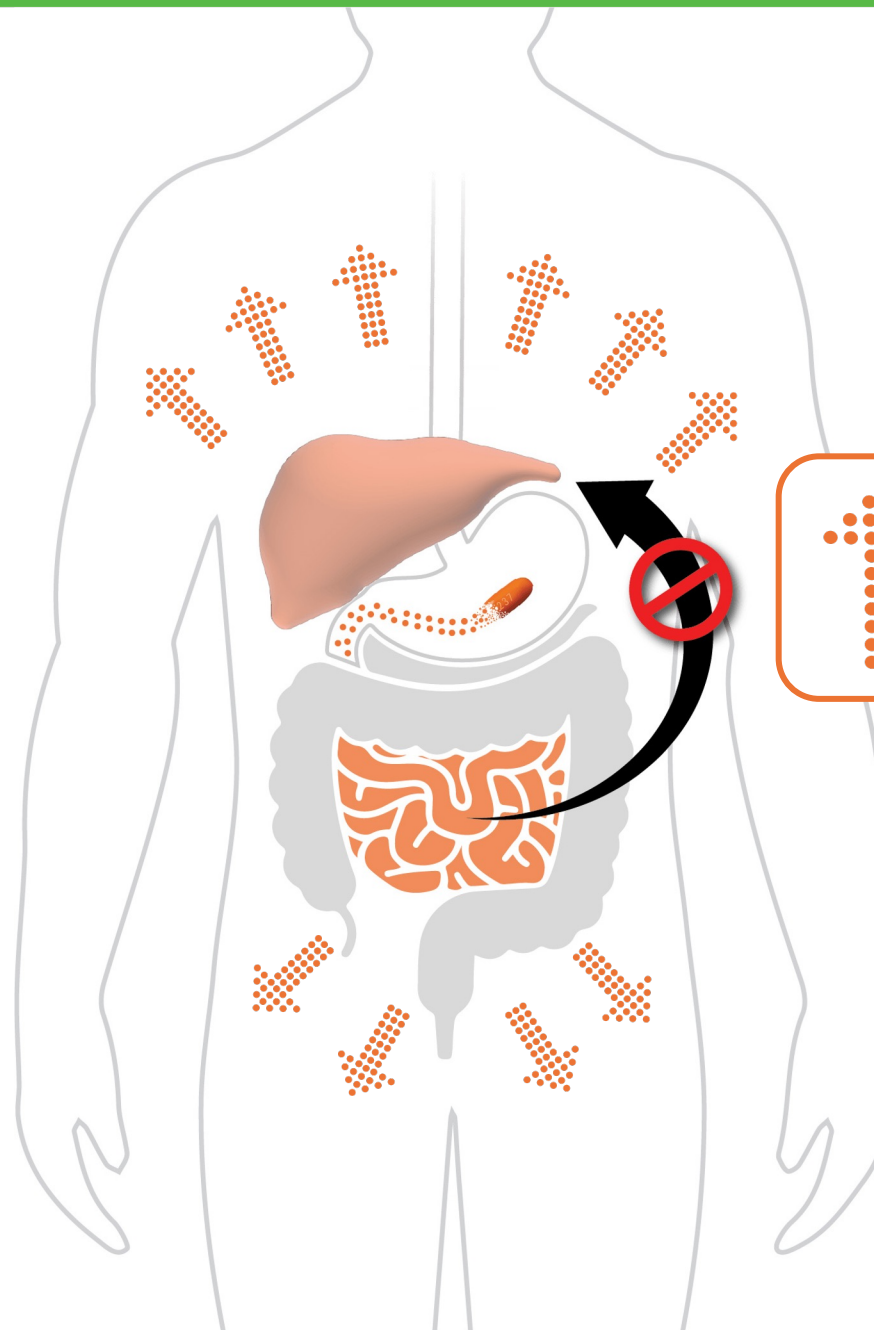
WARNINGS AND PRECAUTIONS

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Increase in hematocrit and polycythemia. High red blood cell counts increase the risk of clots, strokes, and heart attacks.

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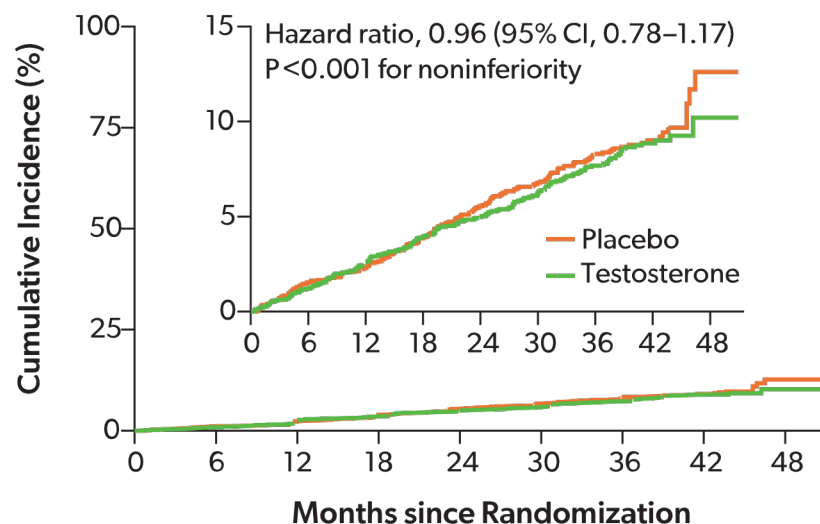
**Testosterone
in systemic
circulation**

JATENZO[®]
(testosterone undecanoate)
Capsules 

Most TRT have a boxed warning around MACE events

However, recent studies in TRAVERSE address MACE events

Primary Cardiovascular Composite Safety End Point: Safety Population



No. at Risk

Placebo	2602	2507	2323	2088	1792	1568	1337	598	33
Testosterone	2596	2504	2339	2120	1829	1605	1380	653	39

Conclusions: In men with hypogonadism and preexisting or a high risk of cardiovascular disease, testosterone-replacement therapy was noninferior to placebo with respect to the incidence of major adverse cardiac events.

73% Physicians feel that TRAVERSE will increase TRT prescriptions

55% However, over half of physicians surveyed still cite safety as prescribing barrier (i.e., need more safety data)

Base: Overall (n=303), Endocrinologists (n=100), Urologists (n=100), PCP+Others (n=103)

Reference: Lincoff AM, Bhasin S, Flevaris P, Mitchell LM, Basaria S, Boden WE, Cunningham GR, Granger CB, Khera M, Thompson IM Jr, Wang Q, Wolski K, Davey D, Kalahasti V, Khan N, Miller MG, Snabes MC, Chan A, Dubcenco E, Li X, Yi T, Huang B, Pencina KM, Trivison TG, Nissen SE; TRAVERSE Study Investigators. Cardiovascular Safety of Testosterone-Replacement Therapy. *N Engl J Med*. 2023 Jul 13;389(2):107-117. doi: 10.1056/NEJMoa2215025. Epub 2023 Jun 16. PMID: 37326322.

The confidence of an established safety profile¹

Number (%) of patients with adverse reactions $\geq 2\%$ in a 4-month study with JATENZO^{®1}

	OVERALL (N=166)
Headache	8 (4.8%)
Hematocrit increased	8 (4.8%)
Hypertension	6 (3.6%)
High-density lipoprotein decreased	5 (3.0%)
Nausea	4 (2.4%)

Three patients (1.8% of 166) had adverse reactions that led to premature discontinuation from the study, including rash (n=1) and headache (n=2).

Adverse reactions were reported in $>2\%$ of patients in all Phase 2 and Phase 3 JATENZO trials combined (N=569): Polycythemia, diarrhea, dyspepsia, eructation, peripheral edema, nausea, increased hematocrit, headache, prostatomegaly, and hypertension.

Important Safety Information (Continued)

WARNINGS AND PRECAUTIONS (continued)

Benign prostatic hyperplasia (BPH). Patients may see worsening signs and symptoms of BPH.

Prostate cancer. Patients treated with androgens may be at increased risk for prostate cancer.

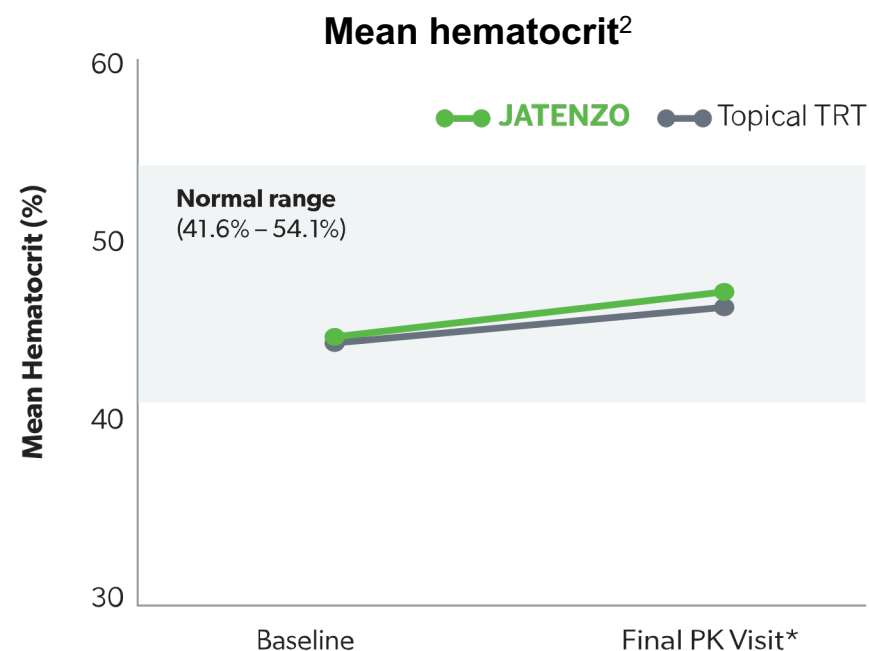
Venous thromboembolic events (VTE). Deep vein thrombosis (DVT) and pulmonary embolism (PE) have been reported in patients using testosterone replacement products like JATENZO.

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Hematocrit levels stayed within normal range for 97% of patients on JATENZO^{®1}

Increases in hematocrit did not lead to any premature discontinuation¹



The following analyses from the inTune clinical study were exploratory. These data points are provided to reflect known pharmacological actions of TRT but were not used to assess safety.³

Evaluate hematocrit approximately every 3 months while the patient is on JATENZO.¹ All testosterone therapies, including JATENZO, require ongoing monitoring of hematocrit levels.⁴

Reference3: 1. Data on file. Clinical study report: CLAR-09009. Tolmar, Inc. 2. Data on file. Clinical study report: CLAR-09007. Tolmar, Inc. 3. Swerdloff RS, Wang C, White WB, et al. A new oral testosterone undecanoate formulation restores testosterone to normal concentrations in hypogonadal men. *J Clin Endocrinol Metab.* 2020;105(8):2515-2531. 4. Bhasin S, Brito JP, Cunningham GR, et al. Testosterone therapy in men with hypogonadism: an Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab.* 2018;103:1715-1744.

Important Safety Information (Continued)

WARNINGS AND PRECAUTIONS (continued)

Abuse. Testosterone has been subject to abuse, typically at doses higher than recommended for the approved indication and in combination with other anabolic androgenic steroids. Testosterone abuse can lead to serious cardiovascular and psychiatric adverse reactions.

Suppression of spermatogenesis. Large doses of androgens, like JATENZO, can suppress spermatogenesis.

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JATENZO[®]
(testosterone undecanoate)
Capsules 



Myth #2

**Orals are not worth
the insurance hassle
for physicians**

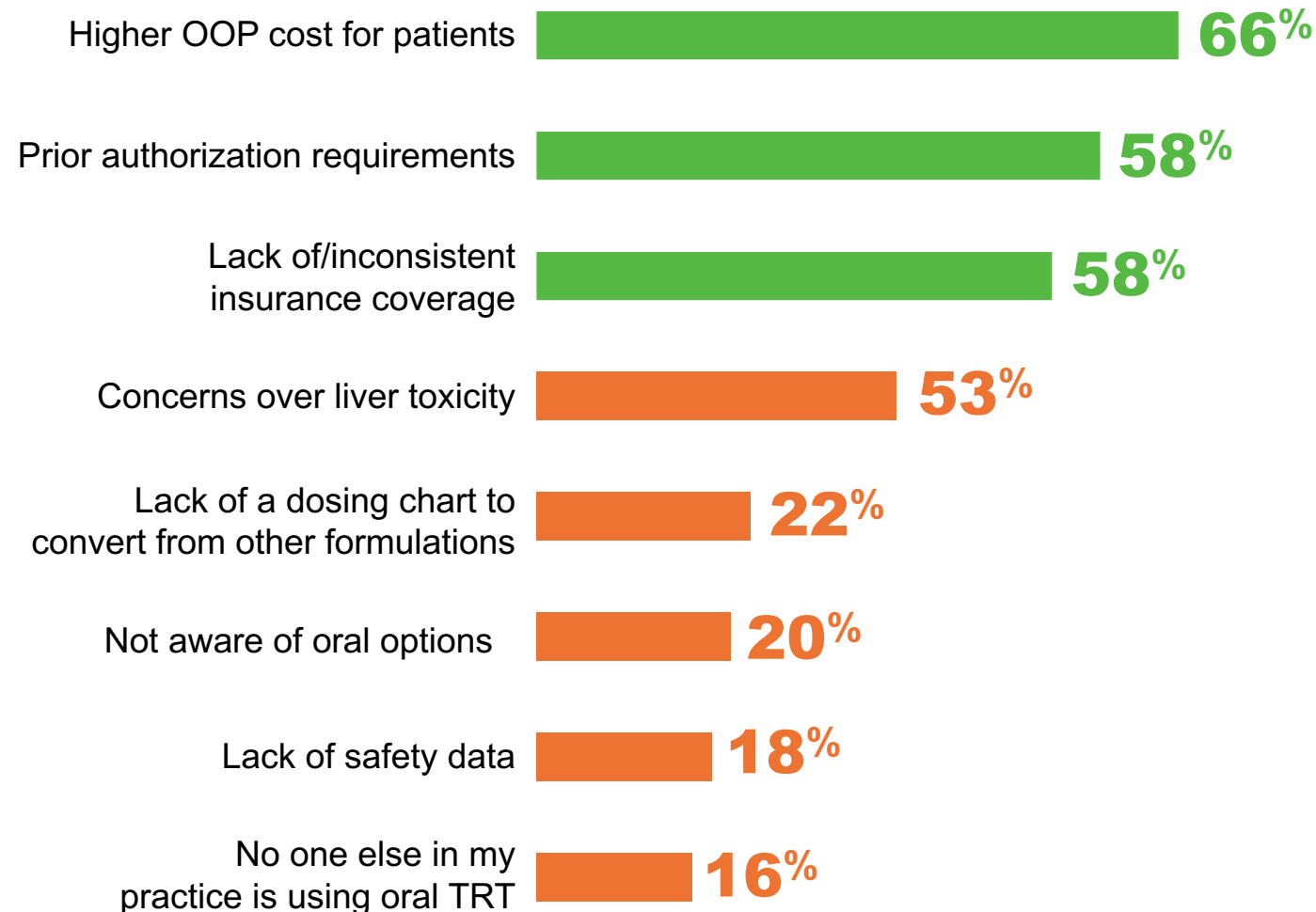
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Insurance Hassles are reported to be the #1 TRT prescribing barrier (above safety concerns)



Barriers in Prescribing an Oral TRT (% of Overall Physicians)



Physicians may believe insurance requirements make branded solutions not worth the effort

Difficult Process:



48%

Physicians say patients need to fail 2 products before prescribing an oral¹

11hr

Endocrinologists report their staff spends almost 11 hours per month to get patients approved for their TRT¹

Generics are Less Hassle:



78%

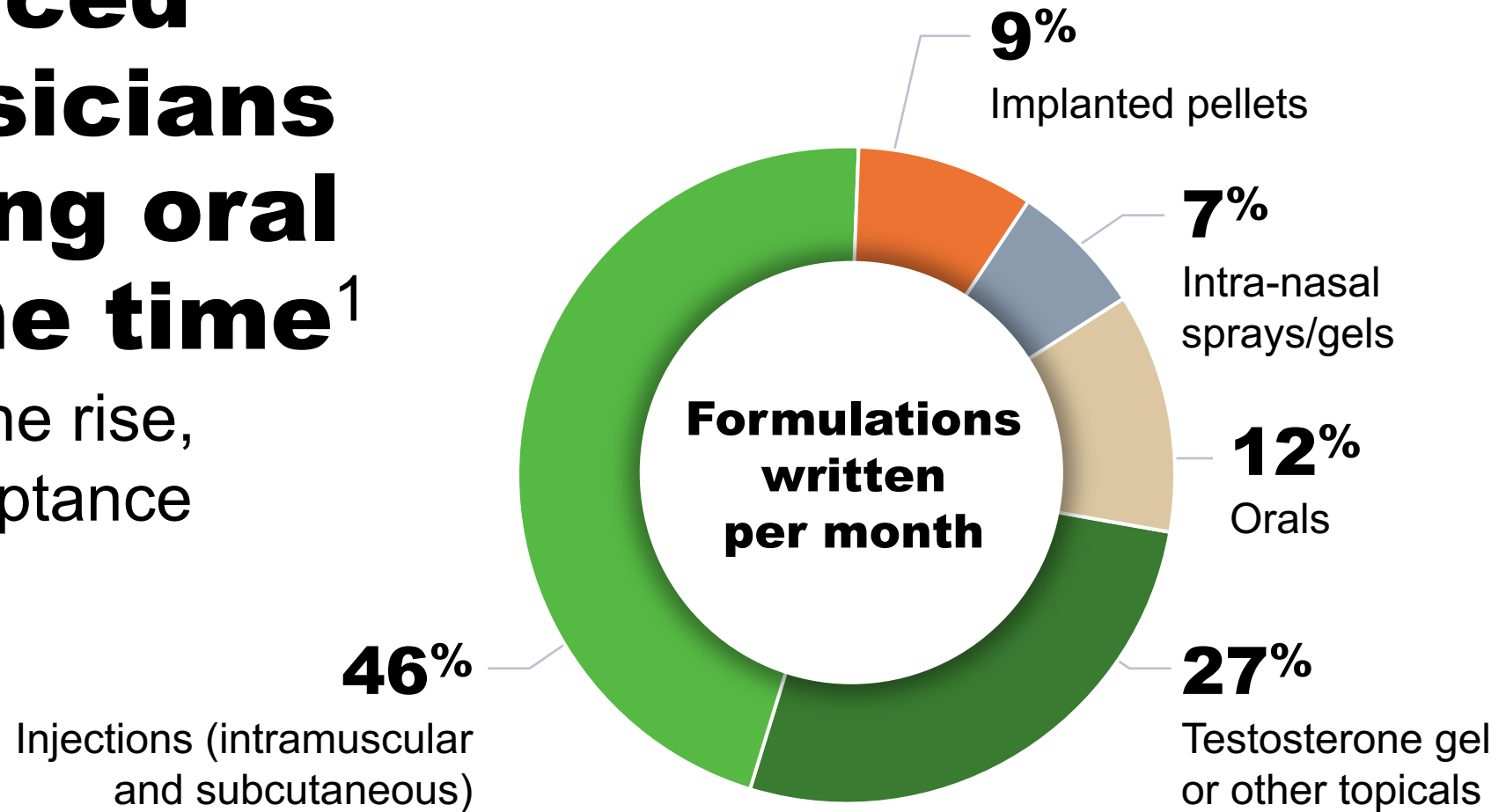
Generics are just easier to prescribe¹

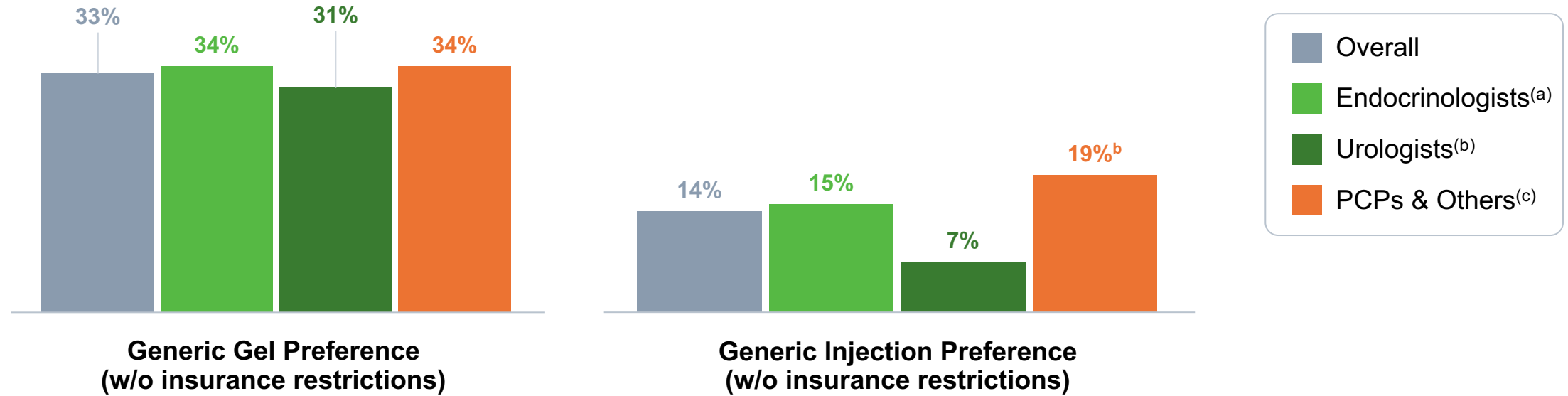
73%

I am often unable to prescribe the brand I want because a patient's insurance does not cover it¹

Experienced TRT physicians are writing oral 12% of the time¹

If usage is on the rise, insurance acceptance will follow





**Generic preference would drop to 33%
if insurance barriers are removed¹**

A/B/C letters indicate significant difference among Specialty at 95% confidence level

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Generics are most prescribed TRT overall

**What have other
endocrinologists found
helpful to address this?**

Through a network pharmacy

Eligible patients with commercial insurance may pay as little as \$0 for every JATENZO® prescription with no cap on copay assistance*

Copay programs also include other benefits for your office with a dedicated team to support:

- Prior authorization submission
- Insurance appeals
- Patient communications and follow-up
- Refill reminders

*** TERMS, CONDITIONS & RESTRICTIONS:** Eligible patients with commercial insurance will pay as little as \$0 for their monthly prescriptions. Eligible patients without commercial insurance may still save up to 50% on their monthly prescription. A valid Prescriber ID# is required on the prescription..

Restrictions: This offer is valid in the United States and Puerto Rico. Offer not valid for prescriptions reimbursed under Medicaid, a Medicare drug benefit plan, TRICARE, or other federal or state health programs (such as medical assistance programs). Cash Discount Cards and other noninsurance plans are not valid as primary under this offer. If the patient is eligible for drug benefits under any such program, the patient cannot use this offer. By using this offer, the patient certifies that he will comply with any terms of his health insurance contract requiring notification to his payer of the existence and/or value of this offer. Offer not valid for patients under 18 years of age. It is illegal to (or offer to) sell, purchase, or trade this offer. This offer is not transferable and is limited to one offer per person. Not valid if reproduced. Void where prohibited by law. Tolmar reserves the right to rescind, revoke, or amend this offer without notice at any time.

Learn more about our network pharmacies



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JATENZO®
(testosterone undecanoate)
Capsules 

**For TRT prescribers,
knowing where to send
prescriptions can make
a difference**

**Specialty pharmacies know how to help
with the insurance process**



Myth #3

**Patients are happy with
any TRT I prescribe**

Injects & gels work for my patients because other
hassles aren't worth it

Physicians and patients may have differing opinions about formulation convenience

Agreement with TRT related statements

(% of Physicians, 5-Point scale, 1- Strongly disagree & 5- Strongly agree)

Disagree Neutral Agree

Patients often complain about injectable testosterone

31%^c

28%^c

41%^b

Patients often complain about topical/spray/gel testosterone

34%^{a,b}

24%

41%

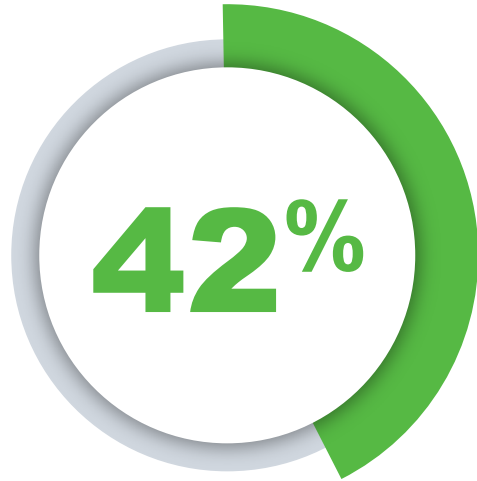
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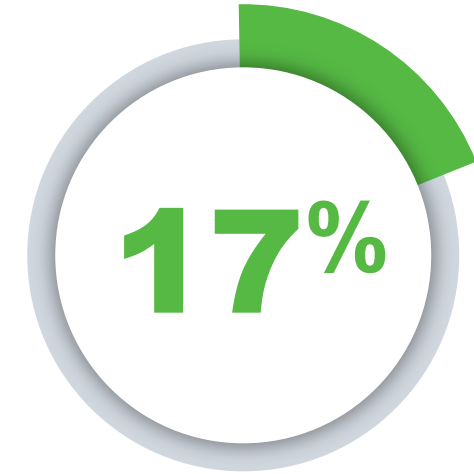
Patients have more difficulty with their TRT than physicians may believe



Required titration after initiation of therapy (i.e., change the dose)¹



Do not take their TRT as prescribed¹

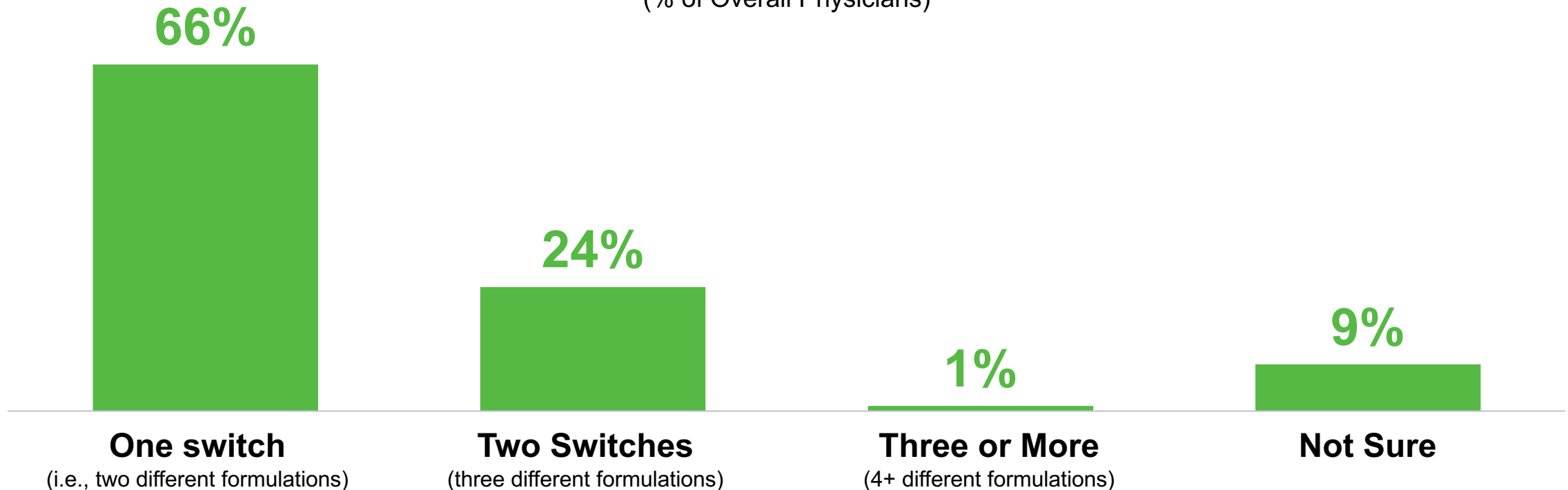


Have been lost to follow-up due to poor administration or compliance issues¹



Physicians report that 66% of patients switched their TRT in a year¹

Number of Switches a TRT Patient Experiences Annually
(% of Overall Physicians)



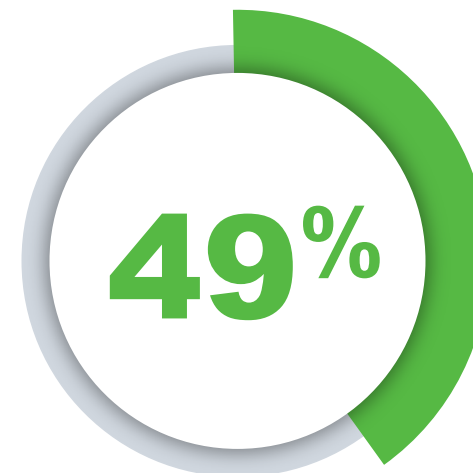
Base: Overall (n=303), Endocrinologists (n=100), Urologists (n=100), PCP+Others (n=103) US physicians fielded in Feb 2024 by SERMO
Reference: 1. Data on file. The Landmark SERMO survey: The state of TRT in 2024. (conducted February 16-March 1, 2024). Tolmar, Inc.

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Physicians agree there are benefits of oral TRT to their patients






Easy and Convenient
Administration¹



Better Patient
Adherence¹

**Formulation choice can
improve adherence for
specific patient types**

JATENZO® offers flexibility that fits his lifestyle and meets his needs¹

	JATENZO 	Injection 	Gel 
Taken orally	✓	✗	✗
Able to be taken on the go	✓	✗	✗
No needles	✓	✗	✓
No in-office administration	✓	✗	✓
No messy gel	✓	✓	✗
No transference concerns	✓	✓	✗

As an oral capsule, JATENZO offers your patients a treatment option with:^{2,3}

- ✓ No injection pain, no procedures
- ✓ No mess, no drying time
- ✓ No skin irritation



Important Safety Information (Continued)

WARNINGS AND PRECAUTIONS

Hepatic adverse events. JATENZO is not known to cause liver adverse events; however, patients should be instructed to report any signs of hepatic dysfunction.

Retention of sodium and water.

Gynecomastia.

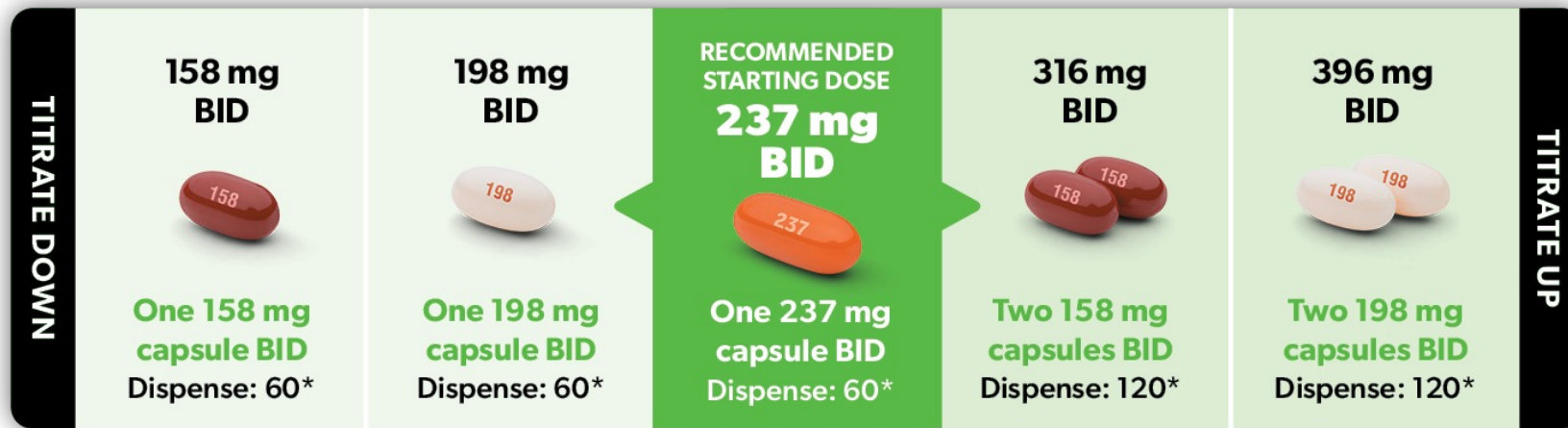
Please see following slides for additional Important Safety Information. Visit JatenzoHCP.com for full Prescribing Information including **BOXED WARNING** on increases in blood pressure.

References: 1. JATENZO (testosterone undecanoate) capsules, for oral use CIII [package insert]. Fort Collins, CO: Tolmar, Inc.; 2023. 2. Shoskes JJ, Wilson MK, Spinner ML. Pharmacology of testosterone replacement therapy preparations. *Transl Androl Urol*. 2016;5(6): 834-843. 3. Petering RC, Brooks, NA. Testosterone therapy: review of clinical applications. *Am Fam Physician*. 2017;96(7):441-449.

Starting on JATENZO is easy

Five dosing options. Three dosage strengths. One oral testosterone.

Depending on patient's serum testosterone concentration, the dose may need to be adjusted¹



JATENZO is taken twice a day with food.¹ No need for a high-fat meal.²
Same dose taken once in the morning and once in the evening

* Dispense as written for 30-day supply of JATENZO. Refer to Prescribing Information for titration instructions.

References: 1. JATENZO (testosterone undecanoate) capsules, for oral use CIII [package insert]. Fort Collins, CO: Tolmar, Inc.; 2023.
2. Swerdloff RS, Wang C, White WB, et al. A new oral testosterone undecanoate formulation restores testosterone to normal concentrations in hypogonadal men. *J Clin Endocrinol Metab*. 2020;105(8):2515-2531.

Important Safety Information (Continued)

WARNINGS AND PRECAUTIONS (continued)

Sleep apnea. Testosterone may potentiate sleep apnea in some patients, especially those with risk factors such as obesity or chronic lung disease.

Changes in the serum lipid profile may require dose adjustment of lipid-lowering drugs or discontinuation of testosterone therapy.

Risk of hypercalcemia.

Please see following slides for additional Important Safety Information. Visit JatenzoHCP.com for full Prescribing Information including BOXED WARNING on increases in blood pressure.



Join the Conversation.

Submit your feedback or questions using the QR code below.



View the Full Presentation.

Download the full report summary to learn more about the study.



Please see last slide for Important Safety Information including BOXED WARNING on increases in blood pressure.



JATENZO[®]
(testosterone undecanoate)
Capsules 



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Important Safety Information for JATENZO (testosterone Undecanoate)

GO BACK ►

Indication and Limitations of Use:

JATENZO® (testosterone undecanoate) capsules, CIII, is an androgen indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone:

- Primary hypogonadism (congenital or acquired)
- Hypogonadotropic hypogonadism (congenital or acquired)

Safety and efficacy of JATENZO in males less than 18 years old have not been established.

IMPORTANT SAFETY INFORMATION FOR JATENZO (testosterone undecanoate)

WARNING: INCREASES IN BLOOD PRESSURE

- **JATENZO can cause blood pressure (BP) increases that can increase the risk of major adverse cardiovascular events (MACE), including non-fatal myocardial infarction, non-fatal stroke and cardiovascular death.**
- **Before initiating JATENZO, consider the patient's baseline cardiovascular risk and ensure blood pressure is adequately controlled.**
- **Periodically monitor for and treat new-onset hypertension or exacerbations of pre-existing hypertension and re-evaluate whether the benefits of JATENZO outweigh its risks in patients who develop cardiovascular risk factors or cardiovascular disease on treatment.**
- **Due to this risk, use JATENZO only for the treatment of men with hypogonadal conditions associated with structural or genetic etiologies.**

CONTRAINDICATIONS

JATENZO is contraindicated in men with carcinoma of the breast or known or suspected carcinoma of the prostate, in women who are pregnant, in men with a known hypersensitivity to JATENZO or its ingredients, or in men with hypogonadal conditions that are not associated with structural or genetic etiologies.

WARNINGS AND PRECAUTIONS

Increase blood pressure and Major Adverse Cardiovascular Events. JATENZO can increase blood pressure, which can increase the risk of MACE, with greater risk in patients with established cardiovascular disease or risk factors for cardiovascular disease.

Increase in hematocrit and polycythemia. High red blood cell counts increase the risk of clots, strokes, and heart attacks.

Benign prostatic hyperplasia (BPH). Patients may see worsening signs and symptoms of BPH.

Prostate cancer. Patients treated with androgens may be at increased risk for prostate cancer.

Venous thromboembolic events (VTE). Deep vein thrombosis (DVT) and pulmonary embolism (PE) have been reported in patients using testosterone replacement products like JATENZO.

Abuse. Testosterone has been subject to abuse, typically at doses higher than recommended for the approved indication and in combination with other anabolic androgenic steroids. Testosterone abuse can lead to serious cardiovascular and psychiatric adverse reactions.

Suppression of spermatogenesis. Large doses of androgens, like JATENZO, can suppress spermatogenesis.

Hepatic adverse events. JATENZO is not known to cause liver adverse events; however, patients should be instructed to report any signs of hepatic dysfunction.

Retention of sodium and water.

Gynecomastia.

Sleep apnea. Testosterone may potentiate sleep apnea in some patients, especially those with risk factors such as obesity or chronic lung disease.

Changes in the serum lipid profile may require dose adjustment of lipid-lowering drugs or discontinuation of testosterone therapy.

Risk of hypercalcemia.

ADVERSE EVENTS

The most common adverse events of JATENZO (incidence $\geq 2\%$) are headache (5%), increased hematocrit (5%), hypertension (4%), decreased HDL (3%), and nausea (2%).

DRUG INTERACTIONS

JATENZO can cause changes in insulin sensitivity or glycemic control and changes in anticoagulant activity. Use of testosterone and corticosteroids concurrently may increase fluid retention. Use of prescription and nonprescription analgesic cold medications with JATENZO have been known to increase blood pressure.

Please visit JatenzoHCP.com full Prescribing Information, including BOXED WARNING on increases in blood pressure.

JATENZO®
(testosterone undecanoate)
Capsules 