Patient Access RESOURCE GUIDE

Tirosint®
(levothyroxine sodium) capsules

Tirosint®-SOL
(levothyroxine sodium) oral solution

For Full Prescribing Information including BOXED WARNING for TIROSINT, visit www.Tirosint.com/prescribinginformation
For Full Prescribing Information including BOXED WARNING for TIROSINT-SOL, visit www.TirosintSOL.com/prescribinginformation

IBSA
Caring Innovation

Tirosint®
(levothyroxine sodium) capsules

INDICATIONS AND USAGE

TIROSINT® (levothyroxine sodium) capsules is L-thyroxine (T4) indicated for adults and pediatric patients 6 years and older with:

- Hypothyroidism - As replacement therapy in primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) congenital or acquired hypothyroidism
- Pituitary Thyrotropin (Thyroid-Stimulating Hormone, TSH) Suppression - As an adjunct to surgery and radioiodine therapy in the management of thyrotropin-dependent well-differentiated thyroid cancer

Limitations of Use:

- TIROSINT is not indicated for suppression of benign thyroid nodules and nontoxic diffuse goiter in iodine-sufficient patients.
- TIROSINT is not indicated for treatment of transient hypothyroidism during the recovery phase of subacute thyroiditis.

IMPORTANT SAFETY INFORMATION

WARNING: NOT FOR THE TREATMENT OF OBESITY OR FOR WEIGHT LOSS

- **Thyroid hormones, including TIROSINT, either alone or with other therapeutic agents, should not be used for the treatment of obesity or for weight loss.**
- **In euthyroid patients, doses within the range of daily hormonal requirements are ineffective for weight reduction.**
- **Larger doses may produce serious or even life-threatening manifestations of toxicity, particularly when given in association with sympathomimetic amines such as those used for their anorectic effects.**

Contraindications

- TIROSINT is contraindicated in patients with uncorrected adrenal insufficiency

Warnings and Precautions

- *Cardiac adverse reactions in the elderly and in patients with underlying cardiovascular disease:* Initiate TIROSINT at less than the full replacement dose because of the increased risk of cardiac adverse reactions, including atrial fibrillation
- *Myxedema coma:* Do not use oral thyroid hormone drug products to treat myxedema coma
- *Acute adrenal crisis in patients with concomitant adrenal insufficiency:* Treat with replacement glucocorticoids prior to initiation of TIROSINT treatment
- *Prevention of hyperthyroidism or incomplete treatment of hypothyroidism:* Proper dose titration and careful monitoring is critical to prevent the persistence of hypothyroidism or the development of hyperthyroidism
- *Worsening of diabetic control:* Therapy in patients with diabetes mellitus may worsen glycemic control and result in increased antidiabetic agent or insulin requirements. Carefully monitor glycemic control after starting, changing, or discontinuing thyroid hormone therapy
- *Decreased bone mineral density associated with thyroid hormone over-replacement:* Over-replacement can increase bone reabsorption and decrease bone mineral density. Give the lowest effective dose

Adverse Reactions

Adverse reactions with levothyroxine therapy are primarily those of hyperthyroidism due to therapeutic overdosage. They include the following:

- *General:* fatigue, increased appetite, weight loss, heat intolerance, fever, excessive sweating
- *Central Nervous System:* headache, hyperactivity, nervousness, anxiety, irritability, emotional lability, insomnia
- *Musculoskeletal:* tremors, muscle weakness, muscle spasm
- *Cardiovascular:* palpitations, tachycardia, arrhythmias, increased pulse and blood pressure, heart failure, angina, myocardial infarction, cardiac arrest
- *Respiratory:* dyspnea
- *Gastrointestinal (GI):* diarrhea, vomiting, abdominal cramps, elevations in liver function tests
- *Dermatologic:* hair loss, flushing, rash
- *Endocrine:* decreased bone mineral density
- *Reproductive:* menstrual irregularities, impaired fertility

Adverse Reactions in Children

Pseudotumor cerebri and slipped capital femoral epiphysis have been reported in children receiving levothyroxine therapy. Overtreatment may result in craniosynostosis in infants and premature closure of the epiphyses in children with resultant compromised adult height. Seizures have been reported rarely with the institution of levothyroxine therapy.

Hypersensitivity Reactions

Hypersensitivity reactions to inactive ingredients (in this product or other levothyroxine products) have occurred in patients treated with thyroid hormone products. These include urticaria, pruritis, skin rash, flushing, angioedema, various GI symptoms (abdominal pain, nausea, vomiting and diarrhea), fever, arthralgia, serum sickness and wheezing. Hypersensitivity to levothyroxine itself is not known to occur.

Drug Interactions

Many drugs and some foods can exert effects on thyroid hormone pharmacokinetics (e.g., absorption, synthesis, secretion, catabolism, protein binding, and target tissue response) and may alter the therapeutic response to TIROSINT. Administer at least 4 hours before or after drugs that are known to interfere with absorption. See full prescribing information for drugs that affect thyroid hormone pharmacokinetics and metabolism.

Tirosint®-SOL
(levothyroxine sodium) oral solution

INDICATIONS AND USAGE

TIROSINT®-SOL (levothyroxine sodium) oral solution is L-thyroxine (T4) indicated in adult and pediatric patients, including neonates, for:

- Hypothyroidism - As replacement therapy in primary (thyroidal), secondary (pituitary), and tertiary (hypothalamic) congenital or acquired hypothyroidism
- Pituitary Thyrotropin (Thyroid-Stimulating Hormone, TSH) Suppression - As an adjunct to surgery and radioiodine therapy in the management of thyrotropin-dependent well-differentiated thyroid cancer

Limitations of Use:

- TIROSINT-SOL is not indicated for suppression of benign thyroid nodules and nontoxic diffuse goiter in iodine-sufficient patients
- TIROSINT-SOL is not indicated for treatment of transient hypothyroidism during the recovery phase of subacute thyroiditis

IMPORTANT SAFETY INFORMATION

WARNING: NOT FOR THE TREATMENT OF OBESITY OR FOR WEIGHT LOSS

- **Thyroid hormones, including TIROSINT-SOL, either alone or with other therapeutic agents, should not be used for the treatment of obesity or for weight loss.**
- **In euthyroid patients, doses within the range of daily hormonal requirements are ineffective for weight reduction.**
- **Larger doses may produce serious or even life-threatening manifestations of toxicity, particularly when given in association with sympathomimetic amines such as those used for their anorectic effects.**

Contraindications

TIROSINT-SOL is contraindicated in patients with:

- Hypersensitivity to glycerol
- Uncorrected adrenal insufficiency

Warnings and Precautions

- *Serious Risks Related to Overtreatment or Undertreatment with TIROSINT-SOL:* Overtreatment or undertreatment with TIROSINT-SOL may have negative effects on growth and development, cardiovascular function, bone metabolism, reproductive function, cognitive function, gastrointestinal function, and glucose and lipid metabolism in adult and in pediatric patients with congenital and acquired hypothyroidism. Proper dose titration and careful monitoring is critical to prevent the persistence of hypothyroidism or the development of hyperthyroidism.
- *Cardiac adverse reactions in the elderly and in patients with underlying cardiovascular disease:* Initiate TIROSINT-SOL at less than the full replacement dose because of the increased risk of cardiac adverse reactions, including atrial fibrillation
- *Myxedema coma:* Do not use oral thyroid hormone drug products to treat myxedema coma
- *Acute adrenal crisis in patients with concomitant adrenal insufficiency:* Treat with replacement glucocorticoids prior to initiation of TIROSINT-SOL treatment
- *Worsening of diabetic control:* Therapy in patients with diabetes mellitus may worsen glycemic control and result in increased antidiabetic agent or insulin requirements. Carefully monitor glycemic control after starting, changing, or discontinuing thyroid hormone therapy
- *Decreased bone mineral density associated with thyroid hormone over-replacement:* Over-replacement can increase bone reabsorption and decrease bone mineral density. Give the lowest effective dose

Adverse Reactions

Adverse reactions associated with TIROSINT-SOL therapy are primarily those of hyperthyroidism due to therapeutic overdosage. They include the following:

- General: fatigue, increased appetite, weight loss, heat intolerance, fever, excessive sweating
- Central Nervous System: headache, hyperactivity, nervousness, anxiety, irritability, emotional lability, insomnia
- Musculoskeletal: tremors, muscle weakness, muscle spasm
- Cardiovascular: palpitations, tachycardia, arrythmias, increased pulse and blood pressure, heart failure, angina, myocardial infarction, cardiac arrest
- Respiratory: dyspnea
- Gastrointestinal (GI): diarrhea, vomiting, abdominal cramps, elevations in liver function tests
- Dermatologic: hair loss, flushing, rash
- Endocrine: decreased bone mineral density
- Reproductive: menstrual irregularities, impaired fertility
- Seizures have been reported rarely with the institution of levothyroxine therapy.

Adverse Reactions in Children

Pseudotumor cerebri and slipped capital femoral epiphysis have been reported in children receiving levothyroxine therapy. Overtreatment may result in craniosynostosis in infants and premature closure of the epiphyses in children with resultant compromised adult height.

Hypersensitivity Reactions

Hypersensitivity reactions to inactive ingredients have occurred in patients treated with thyroid hormone products. These include urticaria, pruritus, skin rash, flushing, angioedema, various GI symptoms (abdominal pain, nausea, vomiting and diarrhea), fever, arthralgia, serum sickness, and wheezing. Hypersensitivity to levothyroxine itself is not known to occur.

Drug Interactions

Many drugs can exert effects on thyroid hormone pharmacokinetics and metabolism (e.g., absorption, synthesis, secretion, catabolism, protein binding, and target tissue response) and may alter the therapeutic response to TIROSINT-SOL. Administer at least 4 hours before or after drugs that are known to interfere with absorption. (See full prescribing information for drugs that affect thyroid hormone pharmacokinetics and metabolism).

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For Full Prescribing Information including BOXED WARNING for TIROSINT-SOL, visit www.TirosintSOL.com/prescribinginformation

Introduction

IBSA Pharma Inc. has developed this resource to help healthcare professionals in their treatment of patients. Information about TIROSINT (levothyroxine sodium) capsules and TIROSINT-SOL (levothyroxine sodium) oral solution, including Full Prescribing Information, may be obtained by visiting www.Tirsoint.com/prescribinginformation or www.TirosintSOL.com/prescribinginformation.

Understanding insurance coverage and Prior Authorization process to ensure patient access to TIROSINT and TIROSINT-SOL

The information in this booklet is intended solely as a resource to assist the staff in physician's offices with certain insurance-related questions. IBSA Pharma makes no representation about the information provided, as insurance coverage, including applicable policies and laws, may be subject to change without notice. These resources may not be conclusive or exhaustive and are not intended to replace the guidance of a qualified, professional advisor.

Information about ICD-10 codes is based on guidance issued by the Centers for Medicare & Medicaid Services (CMS). Consult the relevant manual and/or other guidelines for a description of each code to determine the appropriateness of a particular code and for information on additional codes. This guide includes a list of sample ICD-10 Codes for diagnoses commonly linked to hypothyroidism, but it is not exhaustive. Other codes may apply based on underlying conditions. Inclusion of a code does not confirm medical necessity or prescribing appropriateness or guarantee reimbursement or coverage for TIROSINT or TIROSINT-SOL.

Tirosint® (levothyroxine sodium) capsules
Tirosint®-SOL (levothyroxine sodium) oral solution

Prior Authorization Checklist

Your patients may require a Prior Authorization (PA) after being prescribed TIROSINT or TIROSINT-SOL. This resource may help you prepare the proper PA documentation to submit to the patient's health insurance plan, also known as payer, and may help avoid delays.

—— FOUR ESSENTIALS FOR APPROVAL ——

1. Proper Diagnosis:
Choose the proper diagnosis for your patient
- Primary diagnosis might include, but is not limited to, hypothyroidism, unspecified and/or due to hypothyroidism autoimmune thyroiditis, Hashimoto's thyroiditis, thyroidectomy, or congenital hypothroidism.

2. Documentation of treatment history:
Include the current treatment and patient history, including treatment history from other providers.

3. Previously Used Medications:
Notes of previously used medications, response to therapy, contraindications, interfering concomitant medications, and other medical record documentation.

4. Notes on inadequate symptom control:
Document symptoms and/or absorption challenges for the patient.

—— WHEN SUBMITTING A PRIOR AUTHORIZATION ——

- Be as thorough and accurate as possible when completing a PA to help expedite the process for your patient
- Use this guide to help you prepare information the health insurance plan may require upon submission of the PA
- Make sure all appropriate sections of the PA form are completed, and take note of any questions that require you to attach documentation

Consider gathering the following information to assist when completing the PA forms

Patient Information

☐ **Patient Insurance Information**
- Copy of the patient's prescription card (front and back)
- Copy o the patient's health insurance card (front and back)

☐ **Patient Contact Information**
- Primary phone number
- Email address

Patient Diagnosis/Clinical Information

☐ **Relevant ICD-10-CM Diagnosis Codes**
(See page 7)

☐ **Supporting Clinical Information**
- Lab results and dates

☐ **Patient Treatment History**
- Duration of therapy
- Clinical response
- Allergy
- Strength

☐ **History of Allergy or Intolerance**
Please specify with additional information
- Treatment start date and end date
- Adverse outcomes

Other Resources

☐ **Sample Letters**
- Medical Necessity (see page 8)
- Formulary Exception Request (see page 9)
- Formulary Tiering Exception Request (see page 10)
- Step Therapy Exception Request (see page 11)
- Letter of Appeal (see page 12)
- Continuity of Care (see page 13)

☐ **IBSA Direct Program**
Offers significant patient savings and support
- IBSA Direct Program Information (see page 14)
- Patient Copay Savings Program (see page 15)

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Overview of Relevant ICD-10-CM Diagnosis Codes

The following ICD-10-CM codes are provided for informational purposes only and may assist healthcare professionals and office staff in identifying diagnoses and patient-specific clinical circumstances that may be relevant during coverage and prior authorization review for TIROSINT and TIROSINT-SOL.

ICD-10-CM Diagnosis Codes for Hypothyroidism	Description
E03.9	Hypothyroidism, unspecified
E06.3	Autoimmune thyroiditis, Hashimoto's thyroiditis
E89.0	Post-thyroidectomy/post-procedural hypothyroidism
E03.1	Congenital hypothyroidism without goiter
E03.0	Congenital hypothyroidism with diffuse goiter
E03.8	Other specified hypothyroidism, non-Hashimoto's/ non-congenital
Additional ICD-10-CM Diagnosis Codes Relevant to Certain Patient Circumstances	**Description**
E050	Graves' Disease
C73	Malignant neoplasm of thyroid gland
R13.10*	Dysphagia*
Z79.899*	Ongoing, daily, or routine Proton Pump Inhibitor (PPI) use*
*These ICD-10 Codes are provided as examples and are only relevant to patients prescribed TIROSINT-SOL.	

Notes: Some insurance plans may require that patients try and fail on a generic and/or a branded tablet formulation of levothyroxine and that a clinical justification is provided to support the use of TIROSINT/ TIROSINT-SOL semi-liquid and liquid formulations. The more precise diagnosis and clinical justification that can be provided when submitting a Prior Authorization, the greater the likelihood of getting the product reimbursed.

Disclaimer: The information contained herein is intended for informational purposes only and does not constitute reimbursement, coding, legal, or medical advice. Healthcare professionals are responsible for determining appropriate diagnosis coding based on the patient's clinical presentation, medical record documentation, and applicable coding guidelines. The inclusion of any ICD-10-CM code does not imply coverage, reimbursement, or medical necessity. Payers may apply additional coverage criteria and documentation requirements. Healthcare professionals are encouraged to contact individual payers directly for specific information regarding coverage, coding, and reimbursement policies.

Sample Letter of Medical Necessity

This is an example of a Letter* of Medical Necessity (LMN) that you can use for patients when coverage for either TIROSINT (levothyroxine sodium) capsules or TIROSINT-SOL (levothyroxine sodium) oral solution has been denied by a patient's health insurer.

[To be completed by the prescriber and printed on the letterhead]
[Date]
[Name of health plan}
[Mailing address]

[Patient's name]
Plan identification [Number]
[Date of birth]
[Case Number]

Re: Letter of Medical Necessity for [PRODUCT]

To whom it may concern:

I am writing on behalf of my patient, [PATIENT'S NAME], to document medical necessity for treatment with [PRODUCT].

This letter serves to document that [PATIENT'S NAME] has a diagnosis of [ICD-10 CODE(S)] and needs treatment with [PRODUCT] and that [PRODUCT] is medically necessary for [HIM/HER] as prescribed. On behalf of the patient, I am requesting approval for use and subsequent payment for the treatment.

Patient Medical History and Diagnosis:
[PATIENT'S NAME] is a [AGE] year-old [MALE/FEMALE] diagnosed with [DIAGNOSIS]. [PATIENT'S NAME] has been in my care since [DATE]. As a result of [ICD-10 CODE(S)], my patient [ENTER BRIEF DESCRIPTION OF PATIENT HISTORY].

Additionally, [PATIENT'S NAME] has tried [PREVIOUS THERAPIES] and [OUTCOMES]. The attached medical records document [PATIENT'S NAME]'s clinical condition and medical necessity for treatment with [PRODUCT].

Please contact me at [TELEPHONE NUMBER] to answer any questions regarding this matter.

Sincerely,

[Physician's name and signature]
[Physician's medical specialty]
[Physician's practice name]
[Phone #] [Fax #]
Encl: [ ]
NPI = National Provider Identifier

PM-1021-EN-v3

*Include patient's medical records and supporting documentation, clinical evaluation and other pertinent clinical information including the names, strengths, dosage forms and therapeutic outcomes of prior therapies tried.

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For Full Prescribing Information including BOXED WARNING for TIROSINT-SOL, visit www.TirosintSOL.com/prescribinginformation

Sample Formulary Exception Request

This is an example of a letter* that you can use for patients when either TIROSINT (levothyroxine sodium) capsules or TIROSINT-SOL (levothyroxine sodium) oral solution are not on a health plan's formulary.

[To be completed by the prescriber and printed on the letterhead]
[Date]
[Name of health plan}
[Mailing address]

[Patient's name]
Plan identification [Number]
[Date of birth]
[Case Number]

Re: Letter of Formulary Exception Request for [PRODUCT]

To whom it may concern:

I am writing on behalf of my patient, [PATIENT'S NAME] to request that you approve coverage of [PRODUCT] as a medically necessary treatment for [PATIENT'S NAME]'s [ICD-10 CODE(S)], [DATE OF DIAGNOSIS]. This letter provides information about my patient's medical history, diagnosis, and details regarding the medical necessity of the requested treatment with [PRODUCT].

Summary of Patient's History
[*Note: Exercise your medical judgment and discretion when providing a diagnosis and characterization of the patient's medical condition. You may want to include:*]

- [PATIENT'S HISTORY, DIAGNOSIS, AND CURRENT CONDITION]
- [PATIENT'S PREVIOUS TREATMENTS/AND RESPONSE TO TREATMENT]
- [SUMMARY OF YOUR PROFESSIONAL OPIONION OF THE PATIENT'S PROGNOSIS OR DISEASE PROGRESSION WITHOUT TREATMENT WITH [PRODUCT].]

Rationale for Treatment
Given the patient's medical history and current clinical status, [PATIENT'S NAME] is appropriate for the approved indication for [PRODUCT], and I believe treatment with [PRODUCT] is warranted, appropriate, and medically necessary. The accompanying package insert provides the approved clinical information for [PRODUCT].

Please contact me at [TELEPHONE NUMBER] to answer any questions regarding this matter.

Sincerely,
[Physician's name and signature]
[Physician's medical specialty]
[Physician's practice name]
[Phone #] [Fax #]
Encl: [ ]
NPI = National Provider Identifier

PM-1017-EN-v3

IBSA Group - Public

*Include patient's medical records and supporting documentation, clinical evaluation and other pertinent clinical information including the names, strengths, dosage forms and therapeutic outcomes of prior therapies tried.

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Sample Formulary Tiering Exception Request

This is an example of a letter* that you can use for patients when either TIROSINT (levothyroxine sodium) capsules or TIROSINT-SOL (levothyroxine sodium) oral solution are on a health plan's formulary but placed in a nonpreferred tier with a higher co-pay or co-insurance than a drug placed in a preferred formulary position.

[To be completed by the prescriber and printed on the letterhead]
[Date]
[Name of health plan}
[Mailing address]

[Patient's name]
Plan identification [Number]
[Date of birth]
[Case Number]

Re: Letter of Formulary Tiering Exception for [PRODUCT]

To whom it may concern:

I am writing to request a tiering exception for my patient, [PATIENT'S NAME], who is currently a member of [NAME OF HEALTH PLAN].

The prescription is for [PRODUCT], which is medically appropriate and necessary for this patient who has been diagnosed with [ICD-10 CODE(S)]. I am requesting that [PRODUCT] be made available to my patient as a preferred medication.

In the past, [PATIENT'S NAME] has attempted other treatments for [HIS/HER] condition, but these have failed for the reasons outlined below.

Past Treatment(s)	Start/Stop Dates	Reason(s) for Discontinuing
[Drug name]	[MM/YY] - [MM/YY]	[Please list side effects, lack of efficacy, etc.]
[Drug name]	[MM/YY] - [MM/YY]	[Please list side effects, lack of efficacy, etc.]

The patient's present treatment(s) are as follows:

Current Treatment(s)	Start Date	Dosage
[Drug name]	[MM/YY]	[XX]
[Drug name]	[MM/YY]	[XX]

Currently, [PATIENT'S NAME] has the following unresolved symptoms:

- [Symptom 1]
- [Symptom 2]

Along with this letter, I have enclosed a copy of my patient's medical records and a Letter of Medical Necessity. The letter describes why [PRODUCT] is medically necessary for my patient's care and is a more appropriate clinical option for [HIS/HER] than the preferred drugs listed currently on [HIS/HER] plan's formulary.

[Explain why lower-tiered formulary drugs would not be as effective as product].

Please contact me at [TELEPHONE NUMBER] to answer any questions regarding this matter.

Sincerely,

[Physician's name and signature]
[Physician's medical specialty]
[Physician's practice name]
[Phone #] [Fax #]
Encl: [ ]
NPI = National Provider Identifier

PM-1019-EN-v3

IBSA Group - Public

*Include patient's medical records and supporting documentation, clinical evaluation and other pertinent clinical information including the names, strengths, dosage forms and therapeutic outcomes of prior therapies tried.

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Sample Step Therapy Exception

This is an example of a letter* that you can use for patients when either TIROSINT (levothyroxine sodium) capsules or TIROSINT-SOL (levothyroxine sodium) oral solution requires the patient to try and fail one or more preferred medications before approving coverage for the prescribed therapy.

[To be completed by the prescriber and printed on the letterhead]
[Date]
[Name of health plan}
[Mailing address]

[Patient's name]
Plan identification [Number]
[Date of birth]
[Case Number]

Re: Letter of Step Therapy Exception Request for [PRODUCT]

To whom it may concern:

I am writing to request a **step therapy exception** for my patient, [PATIENT'S NAME], to allow coverage of [PRODUCT] requiring trial of alternative formulary levothyroxine products.

This letter documents that [PATIENT'S NAME] has been diagnosed with [ICD-10 CODE(S)], and requires treatment as follows, which is medically necessary based on their clinical condition:

Current Treatment(s)	Start Date	Dosage
[Drug name]	[MM/YY]	[XX]
[Drug name]	[MM/YY]	[XX]

Medical Justification for Exception (select all that apply):

- ○ The patient has previously tried and failed alternative levothyroxine products, including:

Past Treatment(s)	Start/Stop Dates	Reason(s) for Discontinuation
[Drug name]	[MM/YY] - [MM/YY]	[Please list side effects, lack of efficacy, etc.]
[Drug name]	[MM/YY] - [MM/YY]	[Please list side effects, lack of efficacy, etc.]

- ○ The patient has experienced adverse reactions and/or intolerance to inactive ingredients (e.g., dyes, fillers, excipients) present in other levothyroxine formulations.
- ○ [PRODUCT] is a levothyroxine formulation with minimal excipient ingredients whose presence may contribute to lack of drug tolerability.
- ○ Requiring step therapy may result in drug discontinuation and therapy failure.
- ○ Other:
  _____
  _____

Rationale for Requested Therapy (select all that apply):

[PRODUCT] is the most appropriate therapy for this patient because:

- ○ It avoids excipients that may interfere with drug tolerability.
- ○ It is necessary to maintain therapy adherence and clinically acceptable thyroid hormone levels.
- ○ Other:
  _____
  _____

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Sample Letter of Appeal

This is an example of a letter* that you can use when a patient's prior authorization (PA) request for TIROSINT (levothyroxine sodium) capsules or TIROSINT-SOL (levothyroxine sodium) oral solution is denied by her/his health insurer.

[To be completed by the prescriber and printed on the letterhead]
[Date]
[Name of health plan}
[Mailing address]

[Patient's name]
Plan identification [Number]
[Date of birth]
[Case Number]

Re: Letter of Appeal for [PRODUCT]

To whom it may concern:

I am writing to request a review of a denied claim for [PATIENT'S NAME]. The claim was denied for the following reason(s), listed on the attached Explanation of Benefits (EOB).

[Fill in reason(s) from EOB.]

This letter serves to document that [PATIENT'S NAME] has a diagnosis of [ICD-10 CODE(S)] and needs treatment with [PRODUCT] which is necessary therapy for [HIS/HER] as prescribed. On behalf of the patient, I am requesting approval for use and subsequent payment for the treatment.

Please contact me at [TELEPHONE NUMBER] to answer any questions regarding this matter.

Sincerely,
[Physician's name and signature]
[Physician's medical specialty]
[Physician's practice name]
[Phone #] [Fax #]
Encl: [ ]
NPI = National Provider Identifier

PM-1020-EN-v4

IBSA Group - Public

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Sample Letter Continuity of Care

This is an example of a letter* that you can use for patients currently prescribed and receiving TIROSINT (levothyroxine sodium) capsules or TIROSINT-SOL (levothyroxine sodium) oral solution but a change in insurance coverage, formulary status, utilization management requirements, or provider network participation may disrupt access to treatment. This letter is intended to support continued coverage of the current therapy and help prevent interruptions in patient care.

[To be completed by the prescriber and printed on the letterhead]
[Date]
[Name of health plan}
[Mailing address]

[Patient's name]
Plan identification [Number]
[Date of birth]
[Case Number]

Re: Letter of Continuity of Care for [PRODUCT]

To whom it may concern:

I am writing to request **continuity of care coverage** for my patient, [PATIENT'S NAME] to continue treatment with the following medication(s):

The patient's present treatment(s) are as follows:

Current Treatment(s)	Start Date	Dosage
[Drug name]	[MM/YY]	[XX]
[Drug name]	[MM/YY]	[XX]

[PATIENT'S NAME] has been diagnosed with [ICD-10 CODE(S)] and is currently stable on [PRODUCT]. This medication has been effective in managing their condition, as demonstrated by improved clinical outcomes and/or stabilized laboratory values (e.g., thyroid function tests).

Clinical Rationale for Continuity of Care (select all that apply):

- ○ The patient is currently well-controlled and stable on [PRODUCT].
- ○ Disruption of therapy or switching to an alternative levothyroxine formulation may lead to loss of therapeutic stability.
- ○ In the past, [PATIENT'S NAME] has attempted other treatments for [HIS/HER] condition, but these have failed for the reasons outlined below:

Past Treatment(s)	Start/Stop Dates	Reason(s) for Discontinuing
[Drug name]	[MM/YY] - [MM/YY]	[Please list side effects, lack of efficacy, etc.]
[Drug name]	[MM/YY] - [MM/YY]	[Please list side effects, lack of efficacy, etc.]

- ○ [PRODUCT] has been essential in achieving therapeutic goals for this patient.
- ○ Other:
  _____
  _____

Risk of Therapy Disruption (select all that apply):
Changing medications at this time may result in:

- ○ Fluctuations in thyroid hormone levels.
- ○ Recurrence or worsening of symptoms.
- ○ Increased need for monitoring, dose adjustments, and additional healthcare utilization.
- ○ Lack of tolerability to therapy.
- ○ Other:
  _____
  _____

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IBSA Group - Public

*Include patient's medical records and supporting documentation, clinical evaluation and other pertinent clinical information including the names, strengths, dosage forms and therapeutic outcomes of prior therapies tried.

This information is presented for informational purposes only and is not intended to provide reimbursement or legal advice. Healthcare providers are encouraged to contact third-party payers for specific information about their coverage policies. There is no requirement that any patient or healthcare provider use any IBSA product in exchange for using this template. It is not meant to substitute for a prescriber's independent medical decision-making.

IBSA DIRECT

PATIENTS PAY LESS WITH SAVINGS PROGRAMS

IBSA Direct enables patients with or without health insurance to purchase their IBSA medicine through our network of participating specialty pharmacies and have it delivered to their home.

IBSA Direct Delivers:

EASY ACCESS

IBSA Direct works for people with or without health insurance who order from one of our participating mail-order pharmacies.

TRANSPARENT PRICING

Current prescription costs can be easily accessed by contacting a participating IBSA Direct pharmacy.

FLEXIBLE SUPPLY

Patients can get up to 30 days of therapy at a time, stay consistent with their prescription, and help manage the number of refills.

AVAILABLE DOSES AND FAST DELIVERY

All doses are kept in stock for immediate delivery, which can be expected in most cases within 2 to 3 business days after the order has been processed. Patients will receive reminders when it's time to refill the prescription.

Governmental beneficiaries are excluded, eligibility terms and conditions apply. Visit IBSA Direct: https://tirosint.com/savings-and-support/ or https://tirosintsol.com/patient-savings-resources to see the full terms and conditions.

IBSA medicines are ordered by e-prescription or fax and the process is fast and easy. To get started, simply visit https://www.ibsausa.com/ibsa-direct.html and choose a product using the links provided.

For Full Prescribing Information including BOXED WARNING for TIROSINT, visit www.Tirosint.com/prescribinginformation
For Full Prescribing Information including BOXED WARNING for TIROSINT-SOL, visit www.TirosintSOL.com/prescribinginformation

PATIENT COPAY SAVINGS PROGRAM

Savings for Patients with Commercial Health Insurance

Patients with commercial health insurance can lower their out-of-pocket costs by using the TIROSINT or TIROSINT-SOL Copay Savings Card.

USE AT ANY RETAIL PHARMACY

Eligible, commercially insured patients can use Copay Savings Card at any retail pharmacy

TO ACCESS THE CARD

Cards are available from your IBSA Sales Representative or can be downloaded from our websites, www.tirosint.com or www.tirosintsol.com

CONDITIONS APPLY

Governmental beneficiaries excluded, terms and conditions apply.

For Copay Savings Card Terms and Conditions and Instructions, please visit **https://tirosint.com/savings-and-support/** or **https://tirosintsol.com/patient-savings-resources/ways-to-save/**

Tirosint®
(levothyroxine sodium) capsules

Tirosint®-SOL
(levothyroxine sodium) oral solution

For Full Prescribing Information including BOXED WARNING for TIROSINT, visit www.Tirosint.com/prescribinginformation
For Full Prescribing Information including BOXED WARNING for TIROSINT-SOL, visit www.TirosintSOL.com/prescribinginformation

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Caring Innovation