

SOT Therapy

Patient Guide

What is the SOT THERAPY?

Supportive Oligonucleotide Therapy (SOT) is a process that enables the RGCC lab to identify the specific gene sequences of different targets such as cancer, Lyme, and various viruses and design a specific oligonucleotide therapy. The SOT is uniquely tailored to each patient's needs. It is a small oligonucleotide which is complementary to a specific sequence of individual genes which are related to anti-apoptotic signals inside cancer cells, or genes essential for microorganisms and viruses' survival or metabolism. Apoptosis is another word for programmed cell death. In other words, the SOT molecule has a potent ability to block specific mRNA with a very high rate of specificity, therefore expression of desired gene is inhibited.

How does the SOT THERAPY work?

A patient's blood is sent to the RGCC lab where the scientists identify the appropriate gene that needs to be silenced. Once they detect the potential genes for targeting, they validate these targets both in silico and in vitro. The validation of target ensures the highest specificity and does not interfere with any other targets. Once the different target genes have been validated, then the most appropriate gene is selected and the laboratory creates an oligonucleotide, complementary to the mRNA for a specific region of this gene. This in turn creates an anti-sense therapy.

These molecules are delivered to the clinic where the patient receive the one dose IV treatment. Once the patient receives the SOT molecules, they are at work 24 hours a day, seven days a week for up to six months, inhibiting the appropriate gene.

Go here for an informative video on SOT: <https://www.youtube.com/watch?v=MgVuSSoHrJg>

Is there more information on the full SOT process?

Below is an article which describes exactly how the whole process of ADME is taking place, both for Absorption, Distribution, Metabolism, Excretion.

<https://www.tandfonline.com/doi/full/10.1080/17425255.2021.1992382>

What is the goal of the SOT THERAPY?

To inhibit the expression of proteins which are essential for the cell metabolism and/or survival.

What kind of cancers can be treated with the SOT THERAPY?

- Solid tumors
- Hematologic malignancies

What kind of viruses can be treated with the SOT THERAPY?

- **HHV1/HSV1 — (Human Simplex Virus-Oral-Facial)**
- **HHV2/HSV2 — (Human Simplex Virus-Genital)**
- **HHV6 (A & B) — (Human Herpes Virus 6)**
- **CMV — (Cytomegalovirus)**
- **Coxsackie (Type A & B)**
- **VZV — Varicella-zoster (shingles)**
- **EBV — (Epstein Barr)**
- **HPV (16/18) — Human papillomavirus**
- **HPV (6/11) — Human papillomavirus**
- **HBV — (hepatitis B)**
- **HCV — (hepatitis C)**
- **HIV — (human immunodeficiency virus)-AIDS**
- **HTLV1— (human T-cell lymphotropic virus)**

What species of Lyme and coinfections be treated with the SOT THERAPY at this time?

Borrelia species	Bartonella species	Babesia species	other tick-borne bacterial diseases
<ol style="list-style-type: none"> 1. <i>B. afzelii</i> 2. <i>B. bavariensis</i> 3. <i>B. bissetii</i> 4. <i>B. burgdorferi</i> 5. <i>B. californiensis</i> 6. <i>B. finlandensis</i> 7. <i>B. garinii</i> 8. <i>B. genomospecies</i> 9. <i>B. hermsii</i> 10. <i>B. kurtenbachii</i> 11. <i>B. lusitaniae</i> 12. <i>B. mayonii</i> 13. <i>B. miyamotoi</i> 14. <i>B. recurrentis</i> 15. <i>B. sinica</i> 16. <i>B. turcica</i> 17. <i>B. turicatae</i> 18. <i>B. valaisiana</i> 19. <i>Candidatus Borrelia taylorii</i> 	<ol style="list-style-type: none"> 1. <i>B. bacilliformis</i>, 2. <i>B. elizabethae</i> 3. <i>B. henselae</i>, 4. <i>B. koehlerae</i> 5. <i>B. quintana</i>, 6. <i>B. vinsonii</i>, 	<ol style="list-style-type: none"> 1. <i>Babesia bigemina</i> 2. <i>Babesia bovis</i> 3. <i>Babesia divergens</i> 4. <i>Babesia duncani</i> 5. <i>Babesia microti</i> 6. <i>B. odocoilei</i> 	<ol style="list-style-type: none"> 1. <i>Anaplasma phagocytophilum</i> 2. <i>Rickettsia rickettsia</i> 3. <i>Ehrlichia chaffeensis</i>

What kind of cancers should not be a consideration for the SOT THERAPY?

- CNS cancers

At what cancer stage should a patient consider the SOT THERAPY?

- Any stage is appropriate however, careful evaluation of the patient is important. Patients with a large tumor burden (single or multiple tumors over 5 cm total) are at risk for Tumor Lysis Syndrome and should be evaluated carefully before undergoing the SOT therapy.

Is the SOT THERAPY safe?

- Yes, they have been assessed in thousands of studies for their safety.

Are there any contraindications or disqualifications for the SOT THERAPY?

- Pregnancy or breast feeding
- Recent blood transfusion
- Recent cytotoxic chemotherapy and/or radiotherapy
- Radioactive Seed Therapy
- Delta T. Cell Therapy (GDTC)
- Children under the age of 11 for cancer
- Children under the age of 5 for viral or Lyme

Note: See full list of substances/therapies/treatments and associated time lines below under “**What Needs to be Avoided for SOT Therapy**”

Can the SOT THERAPY be done on children?

- **For Lyme/Viral:** SOT for Lyme for children over the age of 5 (Reason: the sequence of interest has no overlapping parts with human genome)
- **For Cancer:** SOT For malignancies for children over the age of 10 is at the discretion of the Physician. An evaluation of the thymus gland to verify it is atrophic is recommended for a child under the age of 11. (Reason: An overlapping of 60% of the SOT sequence may generate heterodimers between mRNA and SOT which has no consequence in adults, but in children when the clones of auto-epitopes have not been locked then there is a small (but not zero) possibility to create an autoimmune clone of B cells that may generate an autoimmune condition in the future). It’s important that the physician and the parents be made aware of this potential risk.

Are there any possible adverse reactions with the SOT THERAPY?

While SOT is well tolerated, when dealing with living pathogens in a human body there are potential side effects even with a gene silencing therapy like SOT. Some of the common side effects we’ve seen have been:

- Headaches
- Increased fatigue
- Flu like symptoms
- In Cancer - pain at surgical site can occur
- In Cancer - TLS syndrome mainly with large or numerous tumors
- In Lyme or viral - Herxheimer reactions can occur
- In Lyme or viral - co-infections can flare

Are there any risks with the SOT THERAPY with cancer?

- **In cancer** Tumor Lysis Syndrome – TLS (fever, local edema, accumulation of fluid in the area of the tumor, etc.) is a potential risk with SOT and patients should be properly evaluated prior to ordering the therapy. TLS occurs mainly with large or numerous tumors. It is important that physicians are educated on how to treat TLS if administering it to cancer patients at risk for this.

Can the SOT THERAPY be given a half dose?

- It is recommended to administer the SOT at full dose, however when deemed necessary by the healthcare provider, it can be split into half doses
- The second half must be stored -17 to -23 degrees and given in 21 – 30 days.
- If the second half needs to be given over 30 days, it must be stored at -80 degrees

What is included in the cost of the SOT?

- The SOT THERAPY only

What kind of pre-tests are required for the SOT THERAPY for Cancer?

- Positive RGCC test result confirming presence of CTCs
- Must be within six (6) months

What kind of pre-tests are required for the SOT THERAPY for Viral or Lyme?

- Positive test result confirming presence of the targeted pathogen.
- Test result can be PCR or antibody result
- Test result must be serum based results (urine will be accepted)
- Test result must be within six (6) months (date of reporting)
- Test must be from a reputable lab

How much blood is required for the SOT THERAPY?

- 15-25ml whole blood in RGCC vials (1 glass vial) –

NOTE: if ordering one to three SOTs, can send in one full vial of 30ml)

How does the SOT THERAPY need to be stored?

- Each SOT has a life span of six (6) months
- SOT in the dried form can be stored for up to six months if kept in at room temperature and protected from light
- SOT after reconstitution can be stored in -17 to -23 degrees for up to 21 days
- Longer than 21 days it needs to be stored at -80 degrees

How many of the SOT THERAPIES can be given in a year?

- Cancer – Maximum of four (4) total in a 12-month period (must be spaced at a minimum of three months apart)
- Viral or Lyme – Maximum of nine (9) total in a 12-month period (must be spaced at least seven (7) days apart)
- Viral or Lyme – Maximum of four (4) total for the same target in a 12-month period (must be spaced at a minimum of (3) three months apart and must provide updated test result that shows the pathogen is still present before a repeat for the same pathogen will be allowed)

NOTE: SOTs work for a long time and can accumulate in the body and build up

How close together can the SOT THERAPIES be given for multiple targets?

- **For virus or Lyme** – There is a minimum of seven (7) days between two different SOTs. It is never recommended to give more than one SOT on the same day
- **For cancer** – Three (3) to four (4) months apart with a maximum of four (4) in a 12-month period

Can other therapies be given on the same day as the SOT THERAPY?

- No other therapies are allowed on the same day as a SOT administration

What pre-medications are required for the SOT THERAPY?

- **Mandatory:** 4 mg dexamethasone I.V. in a 20–50 ml rapid drip saline solution or slow bolus push in order to counteract the possibility of extravasation of the IV application by stabilizing the veins lumen and allowing more normal distribution of the therapy.
- **Optional:** Famotidine and Acetaminophen are optional but routinely administered as an extra caution at the healthcare providers discretion.

What needs to be avoided before the SOT THERAPY?

- **For Cancer (Apoptosis Inducer):** The patient must be off **ALL** cytotoxic therapies and free radical producing substances **14 days** prior to the blood draw for the SOT production and again prior to the actual administration of the SOT therapy.

REASON: The breakdown of the CTC caused by these substances creates debris that interferes with the therapy's ability to find its target. Allowing time for the body to clear the debris will increase the effectiveness of the therapy.

- **Natural Cytotoxic Substances (IV Substances):** (Includes Vitamin C, Ozone, H₂O, Colloidal Silver, Artesunate, Curcumin, etc.) at least **14 days**
- **Natural Substances (oral supplements):** cytotoxic substances (per patient's Onconomics Plus results) at least **14 days**
- **Off label medications** – such as Ivermectin, FenBen and Itraconazole: **21 days**
- **Chemotherapy** (non-platinum derivative): at least **14 days**
- **Chemotherapy** (platinum derivative): at least **21 days**
- **MOAB or SMW** drugs: at least **14 days**
- **Blood Transfusions:** at least **120 days**
- **Radiation:** at least **14 days**
- **Contrast:** at least **14 days**
- **Surgery** (simple/routine): at least **7–10 days**
- **Surgery** (brain or extensive): minimum of **30 days** based on time of recovery. Could be longer if slow recovery or if the person had some type of adverse reaction. Must be evaluated on a case-by-case basis
- **Fever:** at least **14 days**

- **Hyperthermia** (local/concentrated/microwave ablation): at least **30 days** due to increase in cellular debris released into blood stream
- **Hyperthermia** (generalized/systemic): no waiting
- **Cryoablation**: no waiting
- **Radioactive Seeds**: Patients are permanently not eligible for therapy due to the prolonged and undetermined time of the radiation exposure
- **Gamma Delta T Cell Therapy (GDTC)**: Patients are permanently not eligible for therapy due to the potential interaction with RGCC therapies
- **For Virus/Lyme (V. Antagonist):**
The patient must be off all therapies for **14 days** prior to the blood draw for the SOT. This includes:
 - Antibiotics (oral or IV)
 - Antiviral medications (oral or IV)
 - Anti-parasitic medications (oral or IV)
 - Vitamin C (IV)
 - Colloidal Silver (oral or IV)
 - H2O IV
 - Ozone (IV)
 - Natural Substances (ALL oral supplements that are trying to kill or suppress the same target as the SOT)

What needs to be avoided after the SOT THERAPY?

- **For Cancer (Apoptosis):**
All therapies may be resumed (as outlined above) **14 days** after administration.
 - IV-C can be resumed after 7 days
- **For Virus/Lyme (V. Antagonist):**
All therapies may be resumed (as outlined above) **7 days** after administration.

Note: for Lyme/coinfections: Biofilm busters are recommended after SOT infusion to expose additional targets for the SOT.

Note: Detox supplements such as binders, glutathione, cytokine reducers, etc. will not interfere with the action of the SOT and can be used both pre and post SOT administration. Oral supplements like multi-vitamins, vitamin D, probiotics, etc. also do not need to be stopped pre or post SOT administration.

What follow up tests are required for the SOT THERAPY?

- **For Cancer:** Oncotrace or Oncotrail are recommended every 3–4 months after the administration of the SOT to evaluate the status of the CTC and the immunophenotypes.
- **For Viral or Lyme:** The same lab that was used to order the SOT should be used to evaluate the status of the pathogen 3–4 months after the SOT administration.

Will one SOT THERAPY cover multiple infections?

- No, the SOT targets only a specific region of a gene. If a patient has multiple active infections, then multiple SOT treatments will be needed. One for each infection since each target has its own unique DNA sequence.

What kind of outcome can be expected with the SOT THERAPY?

- **Cancer Patients:** Approximately 78% of cases had a positive clinical outcome (Complete response or Partial response or Stable disease)
- **Virus Infected Patients:** The positive clinical outcome reached 91%
- **Lyme Disease:** Approximately 95% of cases had a positive clinical outcome

Note: Percentages provided above are in lab numbers only