

## **Procedure for Use of Synovetin OA™**

*[Note: Licensee to modify to match specific facility operations.]*

### **Scope**

This procedure is designed to be used in conjunction with the facility normal operating procedures and addresses those aspects which are unique to Synovetin OA™.

A primary objective of this procedure is to ensure that pet owners understand any post-treatment restrictions and instructions and confirm they are willing and able to comply before treatment is initiated and again before the dog is released. In this process flow, there are three interactions with veterinary personnel trained in the use of unsealed sources during which these instructions and restrictions are confirmed. If, at any of those points, such compliance cannot be confirmed then treatment will not be administered or the patient will not be released.

**The following process is summarized in a flow chart in Appendix A**

### **Procedure A: Identification of Candidate Patients for Treatment with Synovetin OA™.**

The purpose of Procedure A is to first elucidate the common behavior pattern of the owner with the dog, second to determine if those behavior patterns create any risk for any household member to exceed the public dose limits and third, if necessary, to examine whether or not owners can modify certain behaviors necessary to comply with the public dose limits. If the medical professional concludes the owner is not willing or able to comply with any limitations necessary to preserve the public dose limits, then treatment will not be offered.

A1. The attending or consulting veterinarian shall examine a dog and determine if Synovetin OA would be a medically appropriate treatment for that patient.

A2. If so, the veterinarian shall discuss treatment options with the owner.

A3. The veterinary staff shall conduct the pre-screening questionnaire with the owner to determine whether the behavior patterns of patient and owners make that patient an appropriate candidate for treatment.

A3.1 The Pre-Screening Questionnaire is contained in Appendix B.

A3.2. Collect information regarding the dog and household members (anyone that shares the residence where the dog lives)

A3.3. Ask the owner to describe the behavior of their dog. Use leading questions that need more than a yes/no answer. Suggested questions include:

A3.3.1. What does your dog typically do during the day?

A3.3.2. Where does it sleep?

A3.3.3. Who primarily interacts with the dog?

A3.3.4. How does the dog interact with family members on a daily basis? For each activity, determine:

A3.3.4.1. What is the interaction?

A3.3.4.2. Which person?

A3.3.4.3. For how long?

A3.3.4.4. At what distance? [Note the owner will typically think of the distance from the dog's body to the closest portion of the owner's anatomy. Attempt to discern the distance from the dog's elbow to the owner's torso and categorize as <1 foot, 1 foot, 3 feet, or more than 3 feet.]

A3.3.5. Are there any other behaviors or interactions we have not discussed yet?

A3.4. Compile the answers to determine the amount of time spent at distances of <1 foot, 1 foot, or 3 feet on a daily basis. The time at more than 3 feet does not need to be summed.

A3.5. Complete the questions on the remainder of the questionnaire.

A3.6. Determine which of the four categories of contact is applicable and explain to owner.

Scenario	Time @ <1 ft per day	Time @ 1 ft per day	Time @ 3 ft per day
Most common	1 min	15 min	4 h
Extended close contact	1 min	3 h	4 h
Extended intermediate contact	1 min	15 min	12 h
Prolong close and intermediate contact	1 min	11 h	9 h

A3.7. Flag any asterisked questions where the answer was yes. Review those in detail and discuss with the owner whether the identified behavior can be changed and if so how. Note any specific behavior modifications on the Pre-Screening Questionnaire and also on the Release Instructions. [Note: The objective is to eliminate or reduce duration of identified behaviors such that the daily interactions with the dog are for no more than 1 minute a day at less than a foot, 15 minutes a day at 1 foot, and 4 hours a day at 3 feet or otherwise reduce interactions to fit into one of the categories listed above.]

A3.8. If the veterinary staff are confident the owner understands the need to comply with public dose limits and can comply with the release instructions, then proceed with ordering Synovetin OA treatment and continue with the following procedures. If the veterinary staff are not confident the owner can comply with the release instructions, exit this procedure and do not offer treatment with Synovetin OA™.

A3.9. If the procedure moves forward, the licensee will retain the signed copy of the Pre-Screening Questionnaire.

## **Procedure B: Review Release Instructions, Scheduling Treatment**

The purpose of this procedure is to ensure that owners appreciate and understand the release instructions they would receive immediately after treatment (including any specific behavior limitations that may have been identified in Procedure A). Veterinary staff will explain that patients cannot be released without a signed copy of the Release Instructions specific to each patient, so care is taken to ensure owners understand those Release Instructions and confirm their ability to comply before treatment is planned. If the owner gives that confirmation, material is ordered, and treatment is scheduled. If the owner does not give that confirmation, then treatment will not be scheduled.

- B1. Review the release instructions with the owner. Confirm that the owner understands all of the restrictions and will be able to comply.
- B2. Order Synovetin OA in accordance with manufacturer requirements and schedule treatment.
- B3. When the Synovetin OA arrives, receive and handle the package in accordance with site shipping and receiving procedure and radiation safety program precautions.

## **Procedure C: Treatment and Release**

In this procedure, the owners are reminded of the Release Instructions prior to treatment. After the dog is treated and the release measurements taken, the medical staff fills in the duration of time the Release Instructions must apply and presents those Release Instructions to the owner for signature. The dog will not be released until the owner signs those Release Instructions. Upon release, the owner is given a copy of the signed release instructions for ongoing reference. The licensee will retain a copy of the signed Release Instructions.

### **C1. Treatment**

- C1.1. On the day of treatment, re-review the Release Instructions with the owner, discuss any behavior modifications that are required.
- C1.2. Follow standard site personnel safety requirements.
- C1.3. Prepare the injection in accordance with the directions on the package insert.
- C1.4. The dog shall be injected by authorized staff.
- C1.5. After the procedure, perform contamination surveys in accordance with the site procedures. Check the treatment site for removable contamination and decontaminate as needed.

### **C2. Release**

- C2.1 Once the dog is recovered and medically stable enough to be released, perform exposure rate surveys of the dog at a distance of 1 meter from the nearest treated elbow. Surveys should be performed at the dog's elbow height anteriorly and left and right laterally. Record the highest reading.
- C2.2 If the highest reading is greater than 0.45 mR/h, the dog must be held at the facility until such time as the highest reading is 0.45 mR/h or less. A decrease in the exposure rate reading of approximately 5% per day can be expected.
  - C2.2.1 If the dog must be held, kennel the dog in the kennel(s) identified for holding dogs treated with Synovetin.
  - C2.2.2 Resurvey the dog periodically (typically daily) until the release exposure rate criteria is met.
  - C2.2.3 Fill in the duration of time on the Release Instructions and present to the owner for signature.
  - C2.2.4 After the owner signs the Release Instructions, release the dog and provide the owner with a copy of the signed Release Instructions. The licensee will retain a copy of the signed Release Instructions.

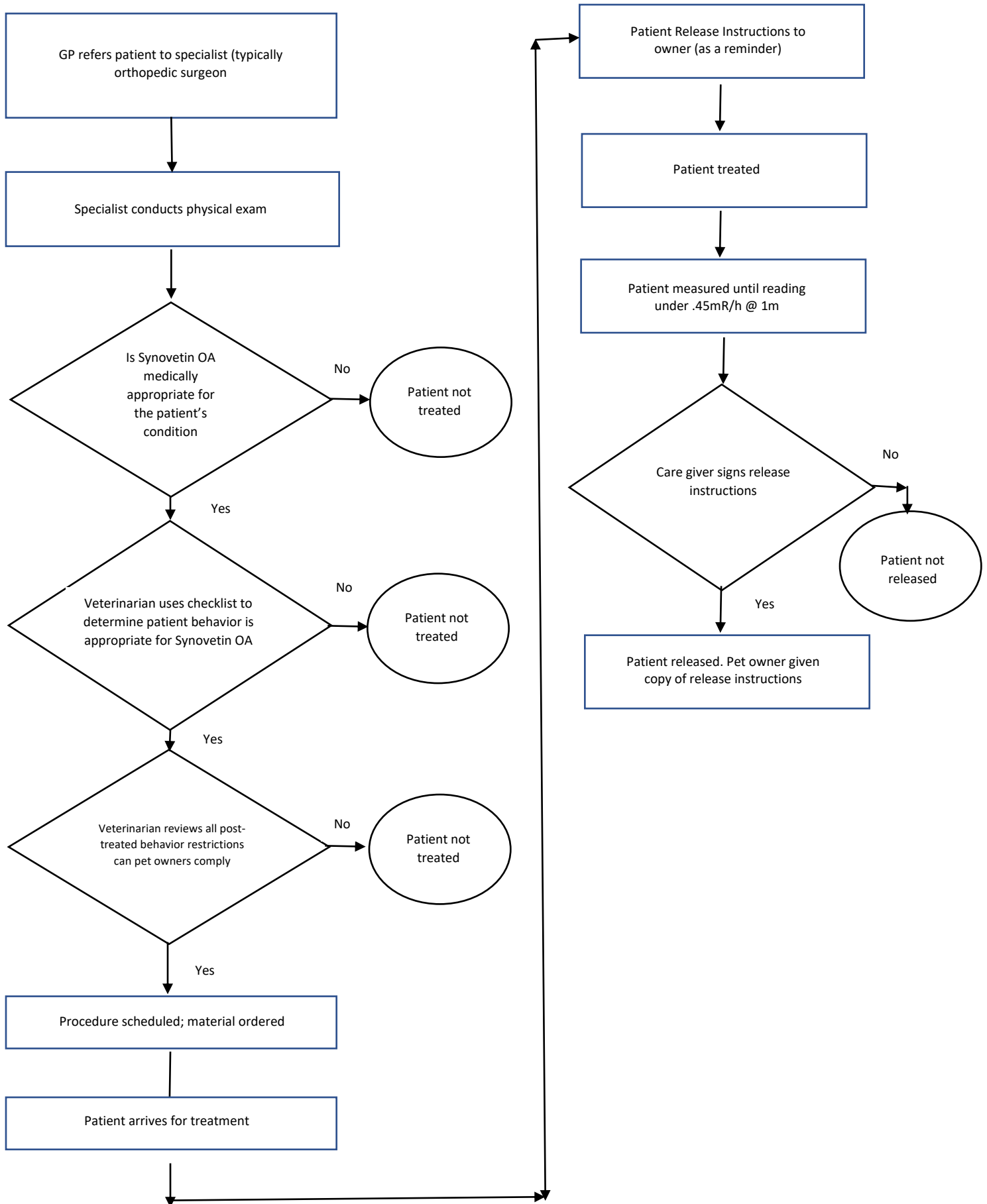
### C3. Documentation

C3.1 Retain in the files a copy of the completed and signed Pre-Screening Questionnaire.

C3.2 Retain in the files a copy of the signed Release Instructions with the recorded release exposure rate.

# Appendix A

## Process Flow Chart



## Appendix B

### Synovetin OA™ Pre-Screening Questionnaire

You and your veterinarian are assessing the suitability of treating your dog with Synovetin OA™ in one or more arthritic joints. Synovetin OA™, a radio-therapeutic device, emits very low amounts of radiation energy within the joint to relieve pain and inflammation over an extended time period. Your dog's coat and surroundings will not be affected, and the activity will naturally decrease over time. To maintain overall exposure below federally established limits, there will be certain procedures to follow in the period after treatment.

Revised 12/19

#### I. Initial Information

Owner Name: \_\_\_\_\_ Date: \_\_\_\_\_

Pet Name: \_\_\_\_\_ Date: \_\_\_\_\_

Person Interviewed: Owner \_\_\_\_\_ Other \_\_\_\_\_

#### II. Household Member Information

Household members: Sex: \_\_\_\_\_ \_\_\_\_\_ \_\_\_\_\_ \_\_\_\_\_ \_\_\_\_\_ \_\_\_\_\_ \_\_\_\_\_ Chad Can you respond to this

Age: \_\_\_\_\_ \_\_\_\_\_ \_\_\_\_\_ \_\_\_\_\_ \_\_\_\_\_ \_\_\_\_\_ \_\_\_\_\_

#### III. General Contact Information

Describe the interaction(s) you have with your pet (direct, close and intermediate activities):

Describe the activity:	Describe the duration:

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Direct activities are <6in (e.g., carrying the dog where the elbow is in contact or lap sitting where the elbow is directly on the torso). Close activities are at 1ft (e.g., feeding, grooming, sleeping, and routine lap-sitting) and intermediate activities are at 3ft (e.g., walking, jogging, and officing).

Are you and your household members able and willing to modify your routine interaction with your pet for the time frames indicated on the release criteria sheet? Yes:\_\_\_ No:\_\_\_

If the answer to the above question is yes, describe proposed modifications:

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Can arrangements for children and pregnant women be modified to minimize close contact?

Yes:\_\_\_ No:\_\_\_ \* N/A:\_\_\_

If the answer to the above question is yes, describe proposed modifications:

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Does your pet currently sleep in the same bed with any household members?

Yes:\_\_\_ No:\_\_\_

If yes, can arrangements be made to avoid this for the indicated time frames on the release criteria sheet? Yes:\_\_\_ No:\_\_\_ \* N/A:\_\_\_

If the answer to the above question is yes, describe proposed modifications:

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Is your pet mobile enough to climb stairs and/or enter and exit a vehicle independently?

Yes:\_\_\_ No:\_\_\_ \* N/A:\_\_\_

If the answer to the above question is no, provide the owner with additional strategies.

Does your pet jump up to beds, furniture, or lap sit?

Yes:\_\_\_ No:\_\_\_

If yes, can arrangements be made to avoid this for the indicated time frames on the release criteria sheet (i.e., not lap sit)? Yes:\_\_\_ No:\_\_\_ \* N/A:\_\_\_

If the answer to the above question is yes, describe proposed modifications:

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Does your pet currently sit in very close proximity (i.e., next to your chair or at your feet) to you for more than 3 hours per day? Yes:\_\_\_ No:\_\_\_

If yes, can arrangements be made to avoid this for the indicated time frames on the release criteria sheet? Yes:\_\_\_ No:\_\_\_ \* N/A:\_\_\_

If the answer to the above question is yes, describe proposed modifications:

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Has the owner been provided with the release criteria sheet?

Yes:\_\_\_ No:\_\_\_\*

Does the owner fully understand the procedure they have arranged for their pet?

Yes:\_\_\_ No:\_\_\_\*

Any “No” checkmark may be contraindicated for the procedure. The authorized user may make an informed decision based on responses, proposed dose to pet, or other clinical factors.

Additional Items Discussed with Animal Owner(s)

Comments

\_\_\_\_Radiation Safety Precautions:

\_\_\_\_\_  
\_\_\_\_\_

\_\_\_\_Importance of modifying time and distance from pet:

\_\_\_\_\_  
\_\_\_\_\_

\_\_\_\_Sleeping Arrangements:

\_\_\_\_\_  
\_\_\_\_\_

\_\_\_\_Added precaution for children and pregnant women:

\_\_\_\_\_  
\_\_\_\_\_

\_\_\_\_What to do if their pet expires:

\_\_\_\_\_  
\_\_\_\_\_

\_\_\_\_What to do if pet needs medical attention:

\_\_\_\_\_  
\_\_\_\_\_

\_\_\_\_Transport/Carrying techniques to minimize contact:

\_\_\_\_\_  
\_\_\_\_\_

\_\_\_\_Other:

\_\_\_\_\_  
\_\_\_\_\_

By signing below, I acknowledge I fully understand the radiation safety aspects associated with Synovetin OA.

Name of Owner or interviewee: \_\_\_\_\_

Signature:

Date:

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Name of individual who conducted interview: \_\_\_\_\_

Signature:

Date:

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Measured Dose Rate at Release (mR/h @ 1m)*	Release Instructions Duration (weeks)					
	0.45	0.4	0.3	0.2	0.1	0.05
<b>Common Contact</b> Up to 1 min/day direct contact, 15 min/day @ 1 ft and 4 h/day @ 3 ft e.g., <i>feeding, grooming, petting, dog walking</i>	2	2	2	2	2	2
<b>Extended Duration Close Contact</b> Up to 1 min/day direct contact, 3 hr/day @ 1 ft and 4 h/day @ 3 ft e.g., <i>holding dog in lap or on the couch, extended grooming, etc.</i>	5	5	3	2	2	2
<b>Extended Duration Intermediate Contact</b> Up to 1 min/day direct contact, 15 min/day @ 1 ft and 12 h/day @ 3 ft e.g., <i>dog rests at the feet of the owner etc.</i>	2	2	2	2	2	2
<b>Prolonged Close and Intermediate Contact</b> Up to 1 min/day direct contact, 11 h/day @ 1ft and 9 h/day @ 3 ft e.g., <i>dog sleeps in the owner's bed etc.</i>	9	8	7	5	3	2

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**Release Instructions following Synovetin OA™ (tin 117m) Canine Arthritis Therapy**

Dog's Name: \_\_\_\_\_ Treatment Date: \_\_\_\_\_

Total Dose Administered: \_\_\_\_\_ mCi Measured Exposure Rate: \_\_\_\_\_ mR/h at 1m

Your dog has been treated with Synovetin OA™ (tin-117m) in one or more arthritic joints. Synovetin OA™, a radio-therapeutic device, emits very low amounts of radiation energy within the joint to relieve pain and inflammation over an extended time period. Your dog's coat and surroundings will not be affected, and the activity will naturally decrease over time. To maintain overall exposure below federally established limits, follow these recommendations for the next \_\_\_\_\_ weeks:

- ✓ Do not sleep with the dog or hold the dog in your lap.
- ✓ Each member of the household should avoid direct contact with the treated joint(s) as much as possible. Daily direct contact should not to exceed 1 minute.
- ✓ Each member of the household should limit close contact to 15 minutes and should limit intermediate contact to 4 hours. Activities such as walking or playing with your dog can continue as usual.
- ✓ Minimize the time that young children and pregnant women spend in close contact with the dog.
- ✓ Avoid boarding your dog or traveling with it by air or across any international borders or very large, organized events (professional sporting events, parades, etc.). Keep a copy of this document should any questions arise.
- ✓ Minimize use of public transportation and staying in public accommodations (e.g., hotels). Transport your dog in its carrier as far from passengers as is reasonable and safe for the dog.
- ✓ If your dog needs emergency care, please inform the provider about its treatment with radiotherapy, and to contact (RSO of facility, at RSO's phone number) with any questions.

Individualized behavior modifications from Pre-Screening Questionnaire:

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If for any reason your dog dies within four months of treatment and you plan to have it cremated, this may be delayed until the radioactivity has decreased to an appropriate level.

If you have any questions, please contact (RSO of facility, at RSO's phone number)

Veterinarian signature: \_\_\_\_\_ Date: \_\_\_\_\_

I have received this information orally and in writing, and I understand it. I have had the opportunity to ask any questions.

Dog owner signature: \_\_\_\_\_ Date: \_\_\_\_\_