

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 veterinary hospital's 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 and can comply with any post-treatment restrictions and instructions before treatment is initiated, and again before the dog is released. In this procedure, there are three interactions with veterinary personnel specifically trained in the use of unsealed sources. If, during any of these interactions compliance with instructions and restrictions cannot be confirmed, then treatment will not be administered, or the dog will not be released.

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

Procedure A: Identification of Dogs for Treatment with Synovetin OA[®].

The purpose of Procedure A is to:

1. Determine the common behavior patterns of the owner(s) with the dog,
2. Determine if those behavior patterns create any risk for any household member to exceed the public dose limits and,
3. If necessary, examine whether or not the owner(s) can modify certain behaviors necessary to comply with the public dose limits.

If the licensee 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 veterinarian will examine the dog and determine if Synovetin OA is medically appropriate.

A2. If so, the veterinarian will discuss Synovetin OA with the owner.

A3. The licensee will conduct the Pre-Screening Questionnaire (Appendix B) with the owner to determine the behavior patterns of the dog and owner(s). The owner will have full knowledge of household member's interaction with the proposed dog.

A3.1. The Pre-Screening Questionnaire is contained in Appendix B. Follow each prompt in the Pre-Screening Questionnaire with assistance from the content included in this Procedure (A3.2.-A3.9.).

A3.2. Collect information regarding the dog(s) 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:

- What does your dog typically do during the day?
- Where does it sleep?
- 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:

- What is the interaction?
- Which person?
- For how long?
- 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 center of the owner's torso and categorize as <1 foot, 1 foot, 3 feet, or more than 3 feet. Round down for added conservatism.]

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 each person spends 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 considered.

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

A3.5.1 The "Additional Items" section of the Pre-Screening Questionnaire is the opportunity for licensee to provide a focused discussion on applicable items to that household. Examples may include the general ALARA principle, strategies to minimize public dose with attention to kids and potentially pregnant members of the household, clarifying dialogue about the distances associated with direct, close, and intermediate contact (anytime less than 1ft falls into the direct category", how to carry a treated dog to minimize dose, reminders that the duration of Release Instructions apply to the behaviors that the owner(s) provide, what to do if their pet is injured or expires, when boarding the treated animal would be appropriate, what to do if the owner thinks any of the limits have been exceeded etc.

A3.6. 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]

A3.6.1 The asterisked questions on the Pre-Screening Questionnaire reflect those conditions which may contraindicate the therapy. If the owner(s) are not able to modify their behaviors to comply with the Release Instructions, the Authorized User may make an informed decision to contraindicate the therapy. There may be other clinical factors which may influence the decision of the AU such as unique time and distance behaviors exhibited by the dog/owner, split time caring for the dog by multiple owners, or other conditions that are not expressly covered in the Questionnaire. The AU has the ultimate responsibility to ensure regulatory limits are met.

A3.7. Determine which of the four categories of dog/owner distance behaviors is applicable and explain to owner. Determination should be conservatively based on each household member's interactions. This table will aid in the determination of the duration of the Release Instructions. Note that only category will apply for the entire household.

Up to 5 min/day direct contact (e.g., joint to torso) 15 min/day @ 1 ft 4 h/day @ 3 ft e.g., feeding, grooming, petting, dog walking
Extended Duration Intermediate Contact
Up to 5 min/day direct contact (e.g., joint to torso) 15 min/day @ 1 ft 12 h/day @ 3 ft e.g., dog rests at the feet of the owner etc.
Extended Duration Close Contact
Up to 5 min/day direct contact (e.g., joint to torso) 3 h/day @ 1 ft 4 h/day @ 3 ft e.g., holding dog in lap or on the couch, extended grooming, etc.
Prolonged Close and Intermediate Contact
Up to 5 min/day direct contact (e.g., joint to torso) 11 h/day @ 1ft 9 h/day @ 3 ft e.g., dog sleeps in the owner's bed etc.

A3.8. If the licensee is confident the owner understands the need to comply with public dose limits and can comply with the Release Instructions, then proceed with scheduling the procedure, ordering Synovetin OA[®] and then continue with the following procedures. If the licensee is 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). The licensee will explain that dogs cannot be released without a signed copy of the Release Instructions specific to each dog, so care is taken to ensure owners understand those Release Instructions and confirm their ability to comply before treatment is planned. Only if the owner gives that confirmation, will treatment be scheduled and Synovetin OA ordered.

B1. Review the Release Instructions with the owner. Confirm that the owner understands and will comply with all of the applicable instructions.

B2. Schedule treatment and then 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 licensee completes the Release Instructions with the appropriate duration, and presents them to the owner for signature. The dog will not be released until the owner signs the 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. Additionally, the licensee should review the Release Instructions with the owner(s) should any follow up care be provided to ensure public dose limits are met.

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 trained staff under the supervision of the AU.

C1.4.1. If the injection site is missed, the owner must be informed that re-treatment can be scheduled 1 year from the initial treatment date.

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 for release, 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.

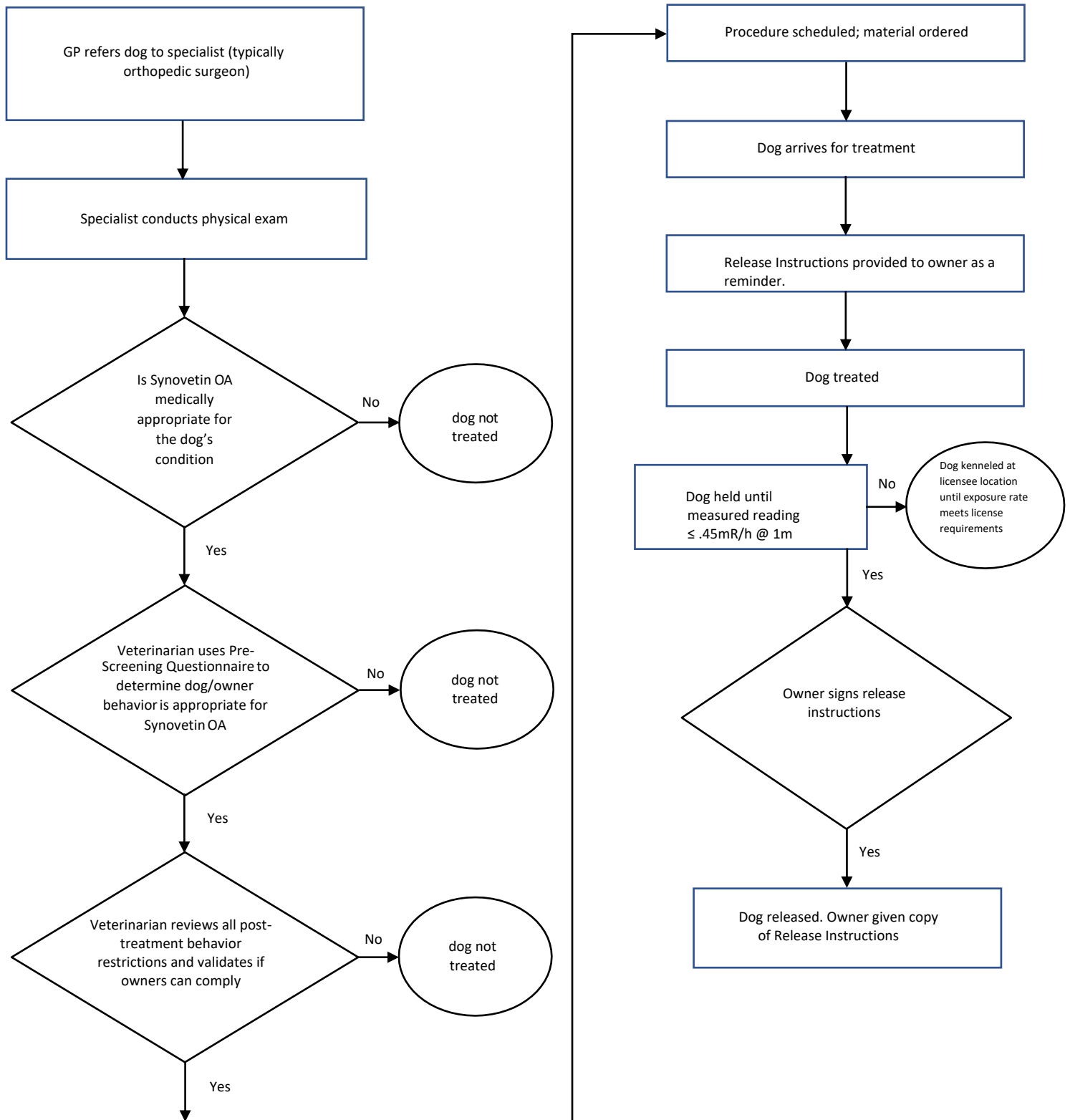
- C2.2.1 If the dog must be held, kennel the dog in the kennel(s) identified for holding dogs treated with Synovetin OA.
- C2.2.2 Resurvey the dog periodically (typically daily) until the release exposure rate criteria is met.
- C2.2.3 Fill in the duration of time on the Release Instructions and present 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.
- C2.2.5 Reinforce to the owner that they may return to their normal interactions with the dog after expiration of the written instruction but that they should continue to practice ALARA (time and distance moderation) for the next two weeks afterwards.
- C2.2.6 Instruct owner that if the dog dies within 20 weeks to contact you. In the event that the dog dies, burial may proceed without restriction. Delay cremation until less than 10 uCi is present (e.g., approximately 20 weeks for largest dog treated with both elbows).

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.
- C3.3 Review compliance to the Release Instructions if any follow up appointments are scheduled before the end of the Release Instruction duration. Investigate any instances where public dose limits may have been exceeded including instances when owners have self-reported exceeding the limitations prescribed in the Release Instructions.

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 treatment, emits ionizing radiation 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.

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I. Initial Information

Owner Name: _____ Date: _____

Pet Name: _____ Date: _____

Person Interviewed: Owner _____ Other _____

II. Household Member Information

Household members: Sex: _____

Age: _____

III. General Contact Information

Describe each household member's interaction(s) with your dog (direct, close and intermediate activities – as defined below the following table):

Person 1	
Activity and type of contact involved (direct, close or intermediate):	Duration:

Direct activities are <1ft (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) **Intermediate** activities are at 3ft (e.g., walking, jogging, and officing).

Person 2	
Activity and type of contact involved (direct, close or intermediate):	Duration:

Add additional pages for other household members, if necessary.

Can interactions with children and pregnant women be modified to minimize close contact with the dog?

Yes:____No:____ * N/A:____

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

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

Yes:____No:____

If yes, can arrangements be made to avoid this for the duration indicated on the Release Instructions?

Yes:____No:____ * N/A:____

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

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 dog jump up to beds or furniture with family members, or lap sit?

Yes:____No:____

If yes, can arrangements be made to avoid this for the duration indicated on the Release Instructions (i.e., not lap sit)?

Yes:____No:____ * N/A:____

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

Does your dog 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 Instructions?

Yes:____No:____ * N/A:____

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

Has the owner been provided with an example Release Instructions sheet? Yes:____No:____*

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

Yes:____No:____*

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 Instructions? Yes:____No:____*

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

*Any “No” checkmark may be contraindicated for the procedure. Contraindication is based on owner responses, proposed dose to pet, or other clinical factors.

Additional Items Discussed with Animal Owner(s)

Comments

____Release Instructions / ALARA considerations:

____Importance of modifying time and distance from pet:

____Sleeping arrangements:

____Added precaution for children and pregnant women:

____What to do if their pet dies or needs medical attention:

____Transport/carrying techniques to minimize contact:

____Other: (such as 1 animal treated per house per year, boarding, traveling, commercial grooming, or tactile treatment)

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

Name of Owner or interviewee: _____

Signature: _____

Date: _____

Name of individual who conducted interview: _____

Signature: _____

Date: _____

Categories of Dog/Owner Distance Behaviors

Measured Exposure Rate at Release (mR/h @ 1m)	0.45	0.4	0.3	0.2	0.1	0.05
Common Contact	Release Instructions Duration (weeks)					
Up to 5 min/day direct contact (e.g. joint to torso) 15 min/day @ 1 ft 4 h/day @ 3 ft e.g., feeding, grooming, petting, dog walking	2	2	2	2	2	2

If Not Common Contact Distance Behaviors, Select One Below

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

Use the above table to fill in the duration (number of weeks) in the following Release Instructions. Assess the duration for each household member that has substantial interaction with the dog. Use the greatest duration value (weeks) in the Release Instructions. For example, if the table indicates a duration of 2 weeks for Person #1 and 3 weeks for Person #2, insert 3 weeks in the Release Instructions. Determination of which dog/owner behavior is decided upon owner answers to the Pre-Screening Questionnaire.

Appendix C: Synovetin OA Release Instructions

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 treatment, emits ionizing radiation 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.

- ✓ Remember to maintain your exposure as low as reasonably achievable (ALARA).
- ✓ Do not sleep with the dog or hold the dog in or near your lap.
- ✓ Each member of the household should avoid direct contact with the treated joint(s) as much as possible. Daily direct contact should be limited to <1 minute. **Direct** activities are those that are <1ft from the dog's treated elbow to the owner's torso (e.g., carrying the dog where the elbow is in contact or lap sitting where the elbow is directly on the torso).
- ✓ 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 with distance limitations maintained. **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).
- ✓ Minimize the time that children and pregnant women spend in close contact with the dog.
- ✓ Avoid long term/daily boarding or commercial grooming of your dog for two weeks or traveling with it by air or across any international borders or very large, organized events (professional sporting events, parades, etc.). Provide 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 and/or as far from passengers as is reasonable and safe for the dog.
- ✓ Follow up care is recommended where your dog received this treatment. If your dog needs emergency care, please inform the provider about its treatment with radiotherapy, and to contact (*insert contact information here*) with any questions.

Individualized behavior modifications from Pre-Screening Questionnaire:

If your dog dies for any reason within 20 week of treatment, contact (*insert contact information here*).

After expiration of these instructions, you may return to normal interactions with your dog but continue to be prudent about extended close contact.

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: _____