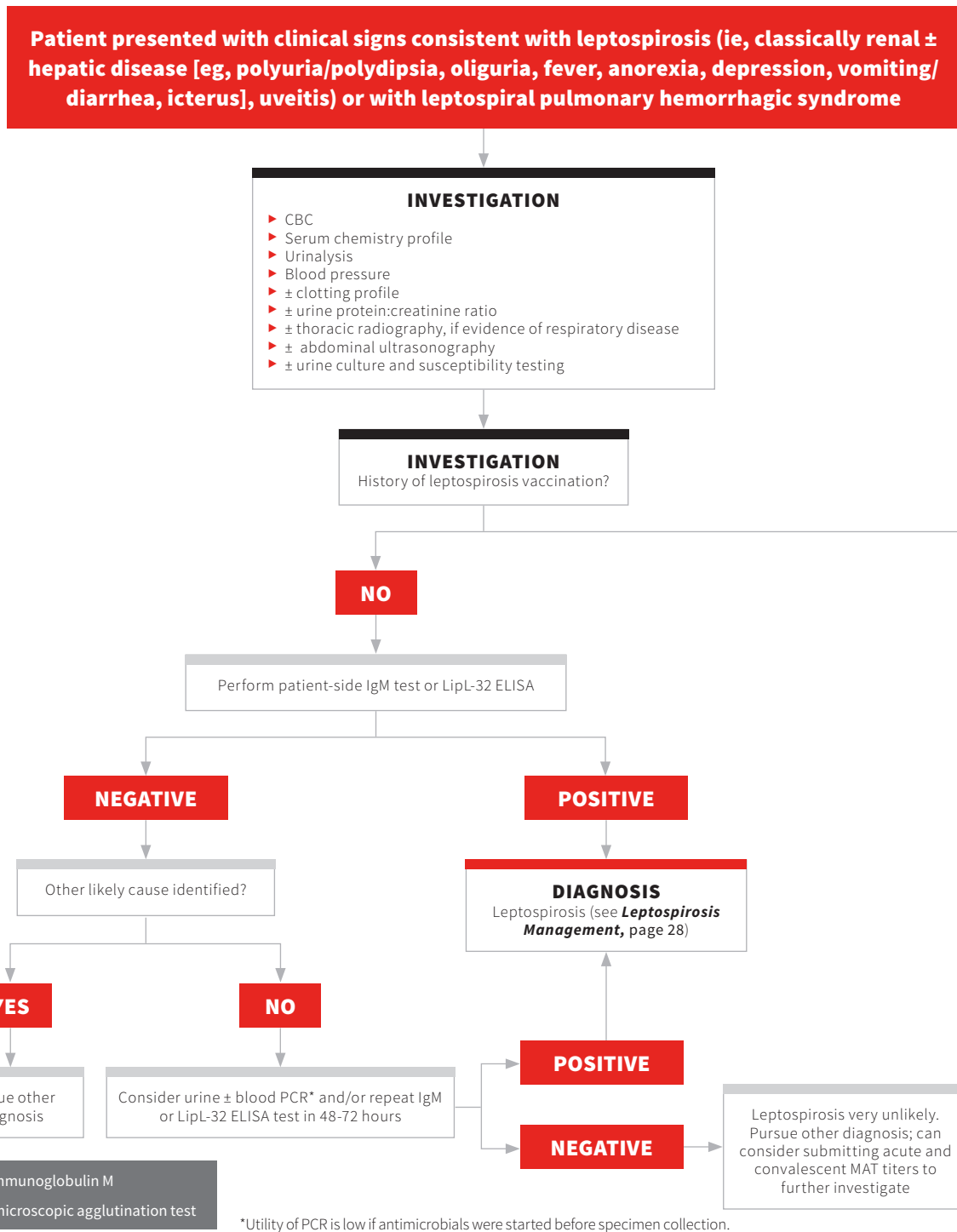


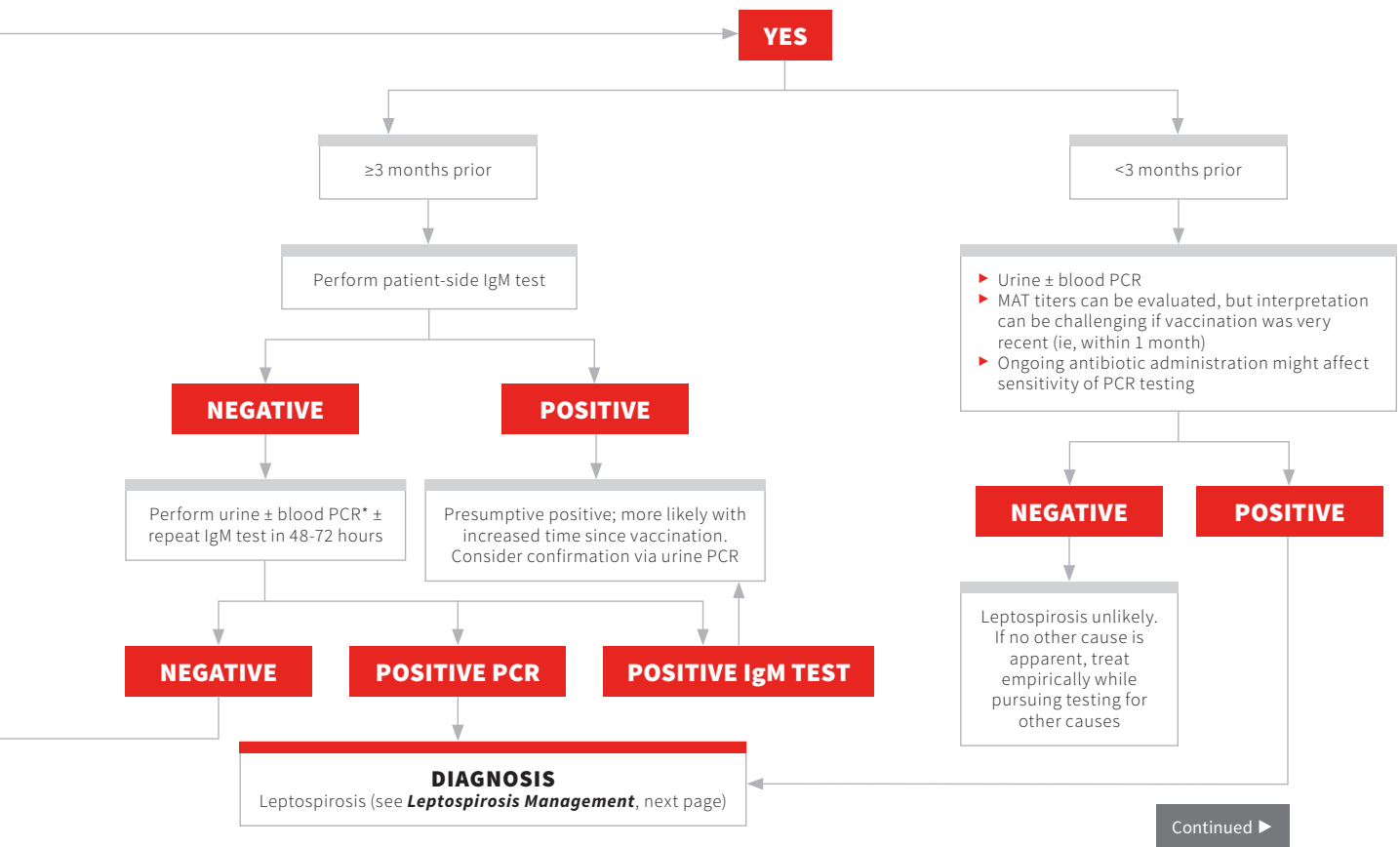
# LEPTOSPIROSIS

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### Leptospirosis Management

Once leptospirosis diagnosis is confirmed, patients should be treated with antimicrobials and supportive care as needed.

#### Antimicrobials

- ▶ If the patient can tolerate oral medication: Doxycycline (5 mg/kg PO every 12 hours) for 14 days<sup>1</sup>
- ▶ If the patient cannot tolerate oral medication: Ampicillin (20 mg/kg IV every 6 hours), then, if possible, de-escalated to oral doxycycline (5 mg/kg PO every 12 hours) for an additional 14 days<sup>1</sup>

#### Supportive Care

- ▶ IV fluids for replacement, diuresis, acid-base balance, and electrolyte maintenance
- ▶ Antiemetics
- ▶ Nutritional support for renal or hepatic injury
- ▶ Renal replacement therapy can be considered in oliguric dogs developing volume overload, severe hyperkalemia, or severe azotemia nonresponsive to medical management.<sup>1</sup>

- ▶ Other care as needed based on clinical syndrome and patient response to treatment

During hospitalization, hydration status should be carefully monitored (ie, measure “ins and outs,” thoracic auscultation, blood pressure), as should BUN/creatinine, acid-base/electrolytes, ± hepatic enzymes (as often as every 24 hours initially). PCV should be rechecked as often as every 24 hours initially, and CBC should be repeated as often as every 48 hours if thrombocytopenia is present and/or in severe cases. Urine specific gravity should also be rechecked every few days once fluid therapy has been discontinued, and clotting factors should be rechecked if abnormal.

Approximately 1 week after the patient is discharged, serum chemistry profile should be repeated, as should CBC if abnormalities were present at the time of discharge. Serum chemistry profile should be rechecked again in 3 to 7 days if results are still abnormal. Urine specific gravity should be monitored regularly if abnormal. ■

**TABLE**

### LEPTOSPIROSIS TESTS & CONSIDERATIONS

Test	Target	Sample type	Patient-side?	Impacted by vaccination?	Impacted by antimicrobial treatment?
MAT	Antibody (IgM and IgG)	Serum	No	Yes	No
Lepto rapid test	Antibody (IgM)	Serum	Yes	Yes	No
LipL-32 Leptospira	Antibody (IgG>IgM)	Serum	Yes	Yes	No
PCR	Antigen	Urine, whole blood	No	No	Potentially

# Elura™

(capromorelin oral solution)

20 mg/mL  
For oral use in cats only

**CAUTION:**  
Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.  
Before using Elura, please consult the product insert, a summary of which follows:

**INDICATION:**  
For management of weight loss in cats with chronic kidney disease.

**DOSAGE AND ADMINISTRATION:**  
Administer ELURA orally at a dose of 2 mg/kg (0.9 mg/lb) or 0.1 mL/kg (0.045 mL/lb) body weight once daily.

**CONTRAINDICATIONS:**  
ELURA should not be used in cats that have a hypersensitivity to capromorelin.

**WARNINGS:**  
Not for use in humans. Keep this and all medications out of reach of children and pets. Consult a physician in case of accidental ingestion by humans.

**For oral use in cats only.**  
Do not use in cats with hypersomatotropism (acromegaly). ELURA may increase serum glucose for several hours after dosing. Use in cats with current or historical diabetes mellitus has not been evaluated and use may not be appropriate.

**PRECAUTIONS:**  
Use with caution in cats that may have cardiac disease or severe dehydration. ELURA causes transient decreases in heart rate and blood pressure up to 4 hours following dose administration. Some cats may exhibit clinical signs of bradycardia or hypotension following administration of ELURA. Use with caution in cats with hepatic dysfunction. Capromorelin is metabolized in the liver in humans and dogs and similar metabolism is expected in the cat. The safe use of ELURA has not been evaluated in cats younger than 5 months old. The safe use of ELURA has not been evaluated in cats that are pregnant, lactating, or intended for breeding.

**ADVERSE REACTIONS:**  
Safety was evaluated in a 56-day field effectiveness study in 176 client-owned cats (118 administered ELURA, 58 administered vehicle control) that received at least one dose. Cats enrolled had ≥5% unintended weight loss and a history of chronic kidney disease (CKD). Cats had a mean age of 15 years and at enrollment 11.4% of the cats were in Stage 1 CKD, 66.5% were in Stage 2, 21.0% were in Stage 3, and 1.1% were in Stage 4. Cats enrolled in the study had a variety of comorbid conditions: dental disease (88.1%), moderate or severe muscle loss (43.2%), heart murmur (28.4%), history of vomiting or underlying gastrointestinal disease (28.4%), hyperthyroidism (13.6%) and hypertension (9.7%).

**Table 1: Adverse Reactions in the Field Effectiveness Study**

Adverse Reaction	ELURA (n=118)	Vehicle Control (n=58)
Vomiting	35 (29.6%)	13 (22.4%)
Hypersalivation	25 (21.2%)	0 (0.0%)
Inappetence	22 (18.6%)	7 (12.0%)
Behavior Change <sup>a</sup>	17 (14.4%)	3 (5.2%)
Lethargy	16 (13.6%)	6 (10.3%)
Anemia	11 (9.3%)	1 (1.7%)
Dehydration	11 (9.3%)	2 (3.4%)
Stage of CKD Increased <sup>b</sup>	10 (8.5%)	3 (5.2%)
Diarrhea	9 (7.6%)	2 (3.4%)
Urinary Tract Infection	8 (6.8%)	2 (3.4%)
Hyperglycemia	8 (6.8%)	2 (3.4%)
Upper Respiratory Infection	7 (5.9%)	1 (1.7%)
Hypercalcemia	7 (5.9%)	0 (0.0%)

Adverse Reaction	ELURA (n=118)	Vehicle Control (n=58)
Facial Skin Lesion	6 (5.1%)	3 (5.2%)
Hyperkalemia	5 (4.2%)	0 (0.0%)
Ataxia	4 (3.4%)	0 (0.0%)
Diabetes Mellitus	1 (0.8%)	0 (0.0%)
Congestive Heart Failure	1 (0.8%)	0 (0.0%)

Note: If an animal experienced the same event more than once, only the first occurrence was tabulated.

<sup>a</sup> Behavior change included hiding from the owner (8 ELURA, 1 vehicle control); owner reported difficulty administering medication (7 ELURA, 1 vehicle control); and redirected aggression to another household cat (2 ELURA, 1 vehicle control).

<sup>b</sup> Two ELURA and 1 vehicle control cat increased by two CKD stages; 8 ELURA and 2 vehicle control cats increased one CKD stage. It could not be determined if the progressive renal disease was the natural course of the pre-existing disease or treatment related.

Hypersalivation was generally associated with dosing and resolved within a few minutes.

Nine cats (8 ELURA and 1 vehicle control) either died or were euthanized during or shortly after the study. Six ELURA cats were euthanized or died from decompensated CKD. One ELURA cat was euthanized after study withdrawal on Day 33 for declining quality of life and recent identification of a new mass. One ELURA cat acutely declined and was euthanized for findings of nodules in both kidneys and diagnosis of sarcoma. The vehicle control cat was euthanized for acute onset of right hindlimb paresis and suspected embolic event. Two additional cats were diagnosed with neoplasia during the study (one ELURA cat with unspecified soft tissue sarcoma and one control cat with mammary adenocarcinoma) but completed the study. In voluntary post-approval reporting for extra-label use of a capromorelin product for dogs, the following adverse events have been reported in cats (listed in decreasing order of reporting frequency): bradycardia, lethargy, hypersalivation, hypotension, behavior change, and vomiting.

To report suspected adverse events, for technical assistance or to obtain a copy of the Safety Data Sheet (SDS), contact Elanco US, Inc. at 1-888-545-5973.

For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or <http://www.fda.gov/reportanimalae>.

**EFFECTIVENESS:**

Effectiveness was demonstrated in a multicenter, prospective, masked, randomized, vehicle-controlled field study. The study enrolled 176 client-owned cats with ≥5% unintended weight loss and a history of chronic kidney disease. The cats enrolled included 96 females and 80 males of various breeds, 4.4 - 22.1 years old with a mean age of 15 years and weighing 1.81 - 6.76 kg. CKD stage was determined based on creatinine at screening according to the International Renal Interest Society (IRIS) 2015 guidelines. All stages were enrolled. Cats were administered ELURA at 2 mg/kg or a matched volume of control once daily by mouth for 56 days. The control was the solution without capromorelin (vehicle control). The primary effectiveness variable was the percent change in body weight from Day 0 to Day 55. Effectiveness was evaluated in 112 cats: 71 cats administered ELURA and 41 cats administered vehicle control. There was a statistically significant difference between the percent change in weight for the ELURA group (+5.2%) compared to the vehicle control group (-1.6%) at Day 55 (p<0.0001). Secondary analysis for percent change in weight at Day 15 and Day 27 demonstrated cats in the ELURA group gained weight throughout the study.

**STORAGE CONDITIONS:**

Store at or below 86°F (30°C)

**HOW SUPPLIED:**

20 mg/mL flavored oral solution in a 15 mL bottle with an oral dosing syringe.

Approved by FDA under NADA # 141-536.

Manufactured for: Elanco US Inc, Greenfield, IN 46140 USA

REV. DATE-10/2020

ELURA, Elanco and the diagonal bar logo are trademarks of Elanco or its affiliates.

PA402828X

## Reference

1. Sykes JE, Hartmann K, Lunn KF, Moore GE, Stoddard RA, Goldstein RE. 2010 ACVIM small animal consensus statement on leptospirosis: diagnosis, epidemiology, treatment, and prevention. *J Vet Intern Med.* 2011;25(1):1-13.

## Suggested Reading

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- Lizer J, Velineni S, Weber A, Krecic M, Meeus P. Evaluation of 3 serological tests for early detection of *Leptospira*-specific antibodies in experimentally infected dogs. *J Vet Intern Med.* 2018;32(1):201-207.
- Midence JN, Leutenegger CM, Chandler AM, Goldstein RE. Effects of recent *Leptospira* vaccination on whole blood real-time PCR testing in healthy client-owned dogs. *J Vet Intern Med.* 2012;26(1):149-152.
- Schuller S, Francey T, Hartmann K, et al. European consensus statement on leptospirosis in dogs and cats. *J Small Anim Pract.* 2015;56(3):159-179.

IgG = immunoglobulin G

IgM = immunoglobulin M

MAT = microscopic agglutination test

