



IOWA MEDICAID DRUG UTILIZATION REVIEW COMMISSION

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Date: April 7, 2015

To: Iowa Medical/Pharmacy Associations

From: Pamela Smith, R.Ph., DUR Project Coordinator

RE: **DUR Recommendation to the Department of Human Services**

The members of the Iowa Medicaid Drug Utilization Review Commission met on April 1, 2015 and voted in favor of making the following recommendations to the Department of Human Services regarding clinical prior authorization criteria. You are receiving this letter because the DUR Commission is interested in the opinions of the members of your organization on this issue.

Hepatitis C Agents

Current Prior Authorization Criteria

Prior authorization is required for direct-acting oral antiviral agents against the hepatitis C virus. Requests for non-preferred agents may be considered when documented evidence is provided that the use of the preferred agents would be medically contraindicated. Payment will be considered under the following conditions:

1. Patient is 18 years of age or older; and
2. Patient's prior treatment history is provided (treatment naïve, prior null responder, partial responder, or relapser); and
3. Documentation of viral load taken within 6 months before beginning therapy; and
4. Viral load will be submitted by prescriber 12 weeks after completion of therapy; and
5. If patient has a history of failed treatment due to non-compliance, documentation that steps have been taken to correct or address the causes of non-compliance are provided; and
6. For patients on a regimen containing ribavirin, the following must be documented on the PA form:
 - a) Patient is not a pregnant female or a male with a pregnant female partner; and
 - b) Women of childbearing potential and their male partners must use two forms of effective contraception (non-hormonal contraception for patients taking Sovaldi™) during treatment and for at least 6 months after treatment has concluded; and
 - c) Documentation that routine monthly pregnancy tests are performed during this time; and
7. Patient has abstained from the use of illicit drugs and alcohol for a minimum of three (3) months as evidenced by a negative urine confirmation test; and

8. Prescriber is an infectious disease specialist, gastroenterologist, hepatologist or other hepatitis specialist.
9. Where applicable, requests for peg-interferon alfa free regimens will be considered on a case-by-case basis for patients with hepatitis C genotype 1 or 4 where peg-interferon alfa is contraindicated. Contraindications include: documented life-threatening side effects; decompensated hepatic disease; autoimmune hepatitis and other autoimmune disorders; a baseline neutrophil count below 1500/ μ L, a baseline platelet count below 90,000/ μ L, or a baseline hemoglobin below 10g/dL; or a history of preexisting unstable cardiac disease.
10. Non-FDA approved or non-compensated combination therapy regimens will not be approved.
11. If patient is recently eligible for Iowa Medicaid, and has been started and stabilized on therapy while covered under a different plan, documentation of how long the patient has been on medication will be required. Patient will be eligible for the remainder of therapy needed, based on established length of therapy for the particular treatment (defined below).
12. Lost or stolen medication replacement requests will not be authorized.
13. The 72-hour emergency supply rule does not apply to oral hepatitis C antiviral agents.

Victrelis

- Patient has a documented diagnosis of hepatitis C genotype 1; and
- Administered in combination with peg-interferon alfa and ribavirin; and
- Patient does not have HIV co-infection; and
- Patient does not have decompensated cirrhosis; and
- Patient has not previously tried or failed therapy with a hepatitis C protease inhibitor; and
- HCV-RNA results are required at treatment week 8, 12, and 24 (including lead in period) for boceprevir (Victrelis™).
- Additional prior authorizations will be considered with documentation of response to treatment, measured by HCV-RNA levels.
- Prior authorizations will be approved for a maximum of 24, 32, or 44 weeks of therapy with boceprevir (Victrelis™) based on response.

Olysio

- Patient has a documented diagnosis of hepatitis C genotype 1; and
- Administered in combination with peg-interferon alfa and ribavirin; and
- Patient does not have HIV co-infection; and
- Patient does not have the NS3 Q80K polymorphism with hepatitis C genotype 1a; and
- The patient is not receiving dialysis or does not have a CrCl < 30 mL/min; and
- Patient has not previously tried or failed therapy with a hepatitis C protease inhibitor; and
- HCV-RNA results are required at treatment week 4 for simeprevir (Olysio™).
- Additional prior authorizations will be considered with documentation of response to treatment, measured by HCV-RNA levels.
- A maximum 12 weeks of therapy will be allowed.

Sovaldi

- The patient is not receiving dialysis or does not have a CrCl < 30 mL/min; and
- Patient does not have decompensated cirrhosis; and
- Documentation the patient has advanced liver disease corresponding to a Metavir score 3 or greater fibrosis as confirmed by one of the following indicators related to staging of liver fibrosis (attach test results/documentation):
 - Liver biopsy confirming a Metavir score \geq F3; or
 - Transient elastography (FibroScan) score \geq 9.5kPa; or
 - FibroSURE (FibroTest) score \geq 0.58; or
 - APRI score > 1.5; or
 - Radiological imaging consistent with cirrhosis (i.e. evidence of portal hypertension); and
 - Physical findings or clinical evidence consistent with cirrhosis.
- Dosing and length of therapy will be based on the following:
 - **Genotype 1:** Patient has a documented diagnosis of hepatitis C genotype 1 (mono-infected or HCV/HIV co-infected) and used in combination with peg-interferon alfa and ribavirin. A maximum 12 weeks therapy will be allowed.
 - **Genotype 2:** Patient has a documented diagnosis of hepatitis C genotype 2 (mono-infected or HCV/HIV co-infected) and used in combination with ribavirin. A maximum 12 weeks of therapy will be allowed.
 - **Genotype 3:** Patient has a documented diagnosis of hepatitis C genotype 3 (mono-infected or HCV/HIV co-infected) and used in combination with ribavirin. A maximum 24 weeks of therapy will be allowed.
 - **Genotype 4:** Patient has a documented diagnosis of hepatitis C genotype 4 (mono-infected or HCV/HIV co-infected) and used in combination with peg-interferon alfa and ribavirin. A maximum 12 weeks of therapy will be allowed.
- **Hepatocellular carcinoma:** Patient has a documented diagnosis of hepatitis C genotype 1, 2, 3, 4 with a diagnosis of hepatocellular carcinoma meeting Milan criteria (awaiting liver transplantation) and in combination with ribavirin for up to 48 weeks or until liver transplantation, whichever comes first. Milan criteria are defined as:
 - One lesion smaller than 5 cm in diameter for subjects with a single lesion;
 - Up to 3 lesions smaller than 3 cm in diameter in subjects with multiple lesions;
 - No extrahepatic manifestations;
 - No vascular invasion.

Harvoni

- Patient has documentation of hepatitis C genotype 1a or 1b; and
- The patient is not receiving dialysis or does not have a CrCl < 30 mL/min; and
- Patient is not co-infected with hepatitis B or HIV; and
- Patient does not have decompensated liver disease; and
- Patient has a contraindication to a preferred peg-interferon alfa plus ribavirin based regimen (e.g. sofosbuvir + peg-interferon + ribavirin); and
- Documentation the patient has advanced liver disease as confirmed by one of the following indicators related to staging of liver fibrosis (attach test results/documentation):
 - Liver biopsy confirming a Metavir score \geq F3; or
 - Transient elastography (FibroScan) score \geq 9.5kPa; or

- FibroSURE (FibroTest) score ≥ 0.58 ; or
- APRI score > 1.5 ; or
- Radiological imaging consistent with cirrhosis (i.e. evidence of portal hypertension); and
- Physical findings or clinical evidence consistent with cirrhosis.
- Dosing and length of therapy will be based on the following:
 - Patient is treatment-naïve without cirrhosis and has a documented pre-treatment baseline HCV RNA less than 6 million IU/mL. A maximum 8 weeks of therapy will be allowed; or
 - Patient is treatment-naïve with or without cirrhosis and has a documented pre-treatment baseline HCV RNA greater than 6 million IU/mL. A maximum 12 weeks of therapy will be allowed; or
 - Patient is treatment-experienced without cirrhosis and experienced failure with a previous treatment regimen that included either peg-interferon alfa + ribavirin or an HCV protease inhibitor + peg-interferon alfa + ribavirin. A maximum 12 weeks of therapy will be allowed; or
 - Patient is treatment-experienced with cirrhosis and experienced failure with a previous treatment regimen that included either peg-interferon alfa + ribavirin or an HCV protease inhibitor + peg-interferon alfa + ribavirin. A maximum 24 weeks of therapy will be allowed.

Proposed Prior Authorization Criteria (changes italicized)

Prior authorization is required for *hepatitis C treatments*. Requests for non-preferred agents may be considered when documented evidence is provided that the use of the preferred agents would be medically contraindicated. Payment will be considered under the following conditions:

1. Patient is 18 years of age or older *and has a diagnosis of chronic hepatitis C*; and
2. *Patient has had testing for hepatitis C virus (HCV) genotype*; and
3. *Patient has an active HCV infection verified by a detectable viral load within 12 months of starting treatment*; and
4. Viral load will be submitted by prescriber 12 weeks after the completion of therapy; and
5. Patient has advanced liver disease corresponding to a Metavir score of 3 or greater fibrosis as confirmed by one of the following:
 - Liver biopsy confirming a Metavir score $\geq F3$; or
 - Transient elastography (FibroScan) score $\geq 9.5\text{kPa}$; or
 - FibroSURE (FibroTest) score ≥ 0.58 ; or
 - APRI score > 1.5 ; or
 - Radiological imaging consistent with cirrhosis (i.e. evidence of portal hypertension); or
 - Physical findings or clinical evidence consistent with cirrhosis; *or*
 - *Patients at highest risk for severe complications: organ transplant, type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (e.g. vasculitis), proteinuria, nephrotic syndrome, or membranoproliferative glomerulonephritis.*
6. Patient's prior treatment history is provided (treatment naïve or *treatment experienced*); and
7. If patient has a history of non-compliance, documentation that steps have been

- taken to correct or address the causes of non-compliance are provided; and
8. Patient has abstained from the use of illicit drugs and alcohol for a minimum of three (3) months as evidenced by a negative urine confirmation test; and
 9. *Patient does not have severe renal impairment (creatinine clearance <30ml/min) or end stage renal disease requiring hemodialysis; and*
 10. *HCV treatment is prescribed by a digestive disease, liver disease, or infectious disease provider practice; and.*
 11. For patients on a regimen containing ribavirin, the following must be documented on the PA form:
 - a) Patient is not a pregnant female or a male with a pregnant female partner; and
 - b) Women of childbearing potential and their male partners must use two forms of effective contraception during treatment and for at least 6 months after treatment has concluded; and
 - c) Monthly pregnancy tests *will be* performed during treatment; and
 12. *Prescriber has reviewed the patient's current medication list and acknowledged that there are no significant drug interactions with the HCV medication.*
 13. *Documentation is provided for patient's who are ineligible to receive interferon or ribavirin.*
 14. Non-FDA approved or non-compensated combination therapy regimens will not be approved.
 15. If patient is recently eligible for Iowa Medicaid, and has been started and stabilized on therapy while covered under a different plan, documentation of how long the patient has been on medication will be required. Patient will be eligible for the remainder of therapy needed, based on established length of therapy for the particular treatment (defined below).
 16. Lost or stolen medication replacement requests will not be authorized.
 17. The 72-hour emergency supply rule does not apply to oral hepatitis C antiviral agents.

CNS Stimulants and Atomoxetine

Current Prior Authorization Criteria

Prior authorization (PA) is required for ADD/ADHD/Narcolepsy agents for patients 21 years of age or older under the following conditions:

1. Attention Deficit Disorder (ADD) or Attention Deficit Hyperactivity Disorder (ADHD) meeting the DSM-IV criteria and confirmed by a standardized rating scale (such as Conners, Vanderbilt, Brown, SNAP-IV). Symptoms must have been present before twelve (12) years of age and there must be clear evidence of clinically significant impairment in two or more environments (social, academic, or occupational).
2. Narcolepsy with diagnosis confirmed with a recent sleep study (ESS, MSLT, PSG).
3. Excessive sleepiness from obstructive sleep apnea/hypopnea syndrome (OSAHS) with documentation of non-pharmacological therapies tried (weight loss, position therapy, CPAP at maximum titration, BiPAP at maximum titration or surgery) and results from a recent sleep study (ESS, MSLT, PSG) with the diagnosis confirmed by a sleep specialist.

Payment for a non-preferred agent will be authorized only for cases in which there is documentation of a previous trial and therapy failure with a preferred agent. *If a non-

preferred long-acting medication is requested, a trial of the preferred immediate release and extended release product of the same chemical entity is required.

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

Proposed Prior Authorization Criteria (*changes italicized*)

Prior authorization (PA) is required for *CNS stimulants and Atomoxetine* for patients 21 years of age or older. *Prior to requesting prior authorization for any covered diagnosis, the prescriber must review the patient's use of controlled substances on the Iowa Prescription Monitoring Program website at <https://pmp.iowa.gov/IAPMPWebCenter/>. Payment for CNS stimulants and Atomoxetine will be considered under the following conditions:*

1. Attention Deficit Disorder (ADD) or Attention Deficit Hyperactivity Disorder (ADHD) meeting the DSM-5 criteria and confirmed by a standardized rating scale (such as Conners, Vanderbilt, Brown, SNAP-IV). Symptoms must have been present before twelve (12) years of age and there must be clear evidence of clinically significant impairment in two or more *current* environments (social, academic, or occupational). *Documentation of a recent clinical visit that confirms the patient continues to require medication to treat the symptoms of ADD/ADHD will be required for renewals or patients newly eligible that are established on medication to treat ADD/ADHD.*
2. Narcolepsy with diagnosis confirmed with a recent sleep study (ESS, MSLT, PSG).
3. Excessive sleepiness from obstructive sleep apnea/hypopnea syndrome (OSAHS) with documentation of non-pharmacological therapies tried (weight loss, position therapy, CPAP at maximum titration, BiPAP at maximum titration or surgery) and results from a recent sleep study (ESS, MSLT, PSG) with the diagnosis confirmed by a sleep specialist.
4. *Binge Eating Disorder (Vyvanse only)*
 - *Patient is 18 to 55 years of age; and*
 - *Patient meets the DSM-5 criteria for Binge Eating Disorder; and*
 - *Patient has documentation of moderate to severe BED, as defined by the number of binge eating episodes per week (number of episodes must be reported); and*
 - *Patient has documentation of non-pharmacologic therapies tried, such as cognitive-behavioral therapy or interpersonal therapy, for a recent 3 month period, that did not significantly reduce the number of binge eating episodes; and*
 - *Patient has documentation of an adequate trial and therapy failure at a therapeutic dose with topiramate and fluvoxamine*
 - *Prescription is written by a psychiatrist or psychiatric nurse practitioner; and*
 - *Patient has a BMI of 25 to 45; and*
 - *Patient does not have personal or family history of cardiovascular disease; and*
 - *Patient has no history of substance abuse; and*
 - *Is not being prescribed for the treatment of obesity or weight loss; and*
 - *Doses above 70mg per day will not be considered.*
 - *Initial requests will be approved for 12 weeks.*

- *Requests for renewal must include documentation of a change from baseline at week 12 in the number of binge days per week.*

DSM-5 Criteria

- i. *Recurrent episodes of binge eating, including eating an abnormally large amount of food in a discrete period of time and has a feeling of lack of control over eating; and*
- ii. *The binge eating episodes are marked by at least three of the following:*
 1. *Eating more rapidly than normal*
 2. *Eating until feeling uncomfortably full*
 3. *Eating large amounts of food when not feeling physically hungry*
 4. *Eating alone because of embarrassment by the amount of food consumed*
 5. *Feeling disgusted with oneself, depressed, or guilty after overeating; and*
- iii. *Episodes occur at least 1 day a week for at least 3 months; and*
- iv. *No regular use of inappropriate compensatory behaviors (e.g. purging, fasting, or excessive exercise) as are seen in bulimia nervosa; and*
- v. *Does not occur solely during the course of bulimia nervosa or anorexia nervosa.*

Moderate to Severe BED

Based on the number of binge eating episodes per week:

Moderate - 4 to 7

Severe – 8 to 13

Extreme – 14 or more

Payment for a non-preferred agent will be authorized only for cases in which there is documentation of a previous trial and therapy failure with a preferred agent. *If a non-preferred long-acting medication is requested, a trial *with* the preferred immediate release and extended release product of the same chemical entity (*methylphenidate class*) or *chemically related agent (amphetamine class)* is required.

The required trials may be overridden when documented evidence is provided that the use of these agents would be medically contraindicated.

Dextromethorphan/Quinidine (Nuedexta)

Current Prior Authorization Criteria

Prior authorization is required for Nuedexta[®]. Payment will be considered under the following conditions:

1. Patients must have a diagnosis of pseudobulbar affect (PBA) secondary to amyotrophic lateral sclerosis (ALS) or multiple sclerosis (MS).
2. A trial and therapy failure at a therapeutic dose with amitriptyline or an SSRI.
3. Initial authorizations will be approved for 12 weeks with a baseline Center for Neurologic Studies Liability Scale (CNS-LS) questionnaire.

4. Subsequent prior authorizations will be considered at 6 month intervals with documented efficacy as seen in an improvement in the CNS-LS questionnaire.

Proposed Prior Authorization Criteria (*changes italicized*)

Prior authorization is required for Nuedexta[®]. Payment will be considered under the following conditions:

1. Patients must have a diagnosis of pseudobulbar affect (PBA) secondary to a *neurological condition*.
2. A trial and therapy failure at a therapeutic dose with amitriptyline or an SSRI; *and*
3. *Patient has documentation of a current EKG (within the past 3 months) without QT prolongation.*
4. Initial authorizations will be approved for 12 weeks with a baseline Center for Neurologic Studies Lability Scale (CNS-LS) questionnaire.
5. Subsequent prior authorizations will be considered at 6 month intervals with documented efficacy as seen in an improvement in the CNS-LS questionnaire.

The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

Chronic Pain Syndromes

Current Prior Authorization Criteria

A prior authorization is required for duloxetine (Cymbalta[®]), pregabalin (Lyrica[®]), and milnacipran (Savella[™]). For patients with a chronic pain diagnosis who are currently taking opioids, as seen in pharmacy claims, a plan to decrease and/or discontinue the opioid(s) must be provided with the initial request. Initial authorization will be given for three (3) months. There must be a significant decrease in opioid use or discontinuation of opioid(s) after the initial three (3) month authorization for further approval consideration. Additional prior authorizations will be considered with documentation of a continued decrease in opioid utilization. Payment will be considered under the following conditions:

1. A diagnosis of **fibromyalgia** (Cymbalta[®], Lyrica[®], and Savella[™])
 - i. A trial and therapy failure at a therapeutic dose with gabapentin plus one of the following: tricyclic antidepressant, SSRI, or SNRI, **WITH**
 - ii. Documented non-pharmacologic therapies (cognitive behavior therapies, exercise, etc.), **AND**
 - iii. Documentation of a previous trial and therapy failure at a therapeutic dose with Savella[™] when Cymbalta[®] and Lyrica[®] are requested.
2. A diagnosis of **postherpetic neuralgia** (Lyrica[®])

A trial and therapy failure at a therapeutic dose with gabapentin plus one of the following: tricyclic antidepressant, topical lidocaine, valproate, or carbamazepine.
3. A diagnosis of **diabetic peripheral neuropathy** (Cymbalta[®] and Lyrica[®])

A trial and therapy failure at a therapeutic dose with gabapentin plus one of the following: tricyclic antidepressant or topical lidocaine.
4. A diagnosis of **partial onset seizures**, as adjunct therapy (Lyrica[®])

5. A diagnosis of **major depressive disorder** or **generalized anxiety disorder** (Cymbalta[®])
6. A diagnosis of **chronic musculoskeletal pain** (Cymbalta[®])

A trial and therapy failure at a therapeutic dose with at least two drugs from two distinct therapeutic classes from the following: NSAIDs, opioids, tramadol, or tricyclic antidepressants.

Requests for concomitant use of these agents for an indicated chronic pain diagnosis may only be considered once each agent has been tried at maximum tolerated dose separately. Duplicate use of drugs from the same therapeutic category will not be considered. Requests for doses above the manufacturer recommended dose will not be considered.

Proposed Prior Authorization Criteria (*changes italicized*)

A prior authorization is required for pregabalin (Lyrica[®]) and milnacipran (Savella[™]). *These drugs will be considered for their FDA indication(s) and other conditions as listed in the compendia.* Requests for doses above the manufacturer recommended dose will not be considered. For patients with a chronic pain diagnosis who are currently taking opioids, as seen in pharmacy claims, a plan to decrease and/or discontinue the opioid(s) must be provided with the initial request. Initial authorization will be given for three (3) months. There must be a significant decrease in opioid use or discontinuation of opioid(s) after the initial three (3) month authorization for further approval consideration. Additional prior authorizations will be considered with documentation of a continued decrease in opioid utilization. Payment will be considered under the following conditions:

1. A diagnosis of **fibromyalgia** (Lyrica[®] and Savella[™])
 - a. A trial and therapy failure at a therapeutic dose with gabapentin plus one of the following *preferred generic agents*: tricyclic antidepressant, SSRI, or SNRI, **WITH**
 - b. Documented non-pharmacologic therapies (cognitive behavior therapies, exercise, etc.).
2. A diagnosis of **postherpetic neuralgia** (Lyrica[®])

A trial and therapy failure at a therapeutic dose with gabapentin plus one of the following: tricyclic antidepressant, topical lidocaine, or valproate.
3. A diagnosis of **diabetic peripheral neuropathy** (Lyrica[®])

A trial and therapy failure at a therapeutic dose with gabapentin plus one of the following: tricyclic antidepressant, *duloxetine* or topical lidocaine.
4. A diagnosis of **partial onset seizures**, as adjunct therapy (Lyrica[®])

~~Requests for concomitant use of these agents for an indicated chronic pain diagnosis may only be considered once each agent has been tried at maximum tolerated dose separately. Duplicate use of drugs from the same therapeutic category will not be considered.~~

Sedative/Hypnotics Non-Benzodiazepines

Current Prior Authorization Criteria

Preferred agents are available without prior authorization (PA). Although intermittent therapy is recommended, quantity limits will allow for 30 tablets per 30 days supply without PA for preferred medications. Prior authorization is required for all non-preferred non-benzodiazepine sedative/hypnotics. Payment for non-preferred non-benzodiazepine sedative/hypnotics will be authorized only for cases in which there is documentation of a previous trial and therapy failure with the preferred agent(s). Payment for non-preferred non-benzodiazepine sedative/hypnotics will be considered when there is:

1. A diagnosis of insomnia.
2. Medications with a side effect of insomnia (i.e. stimulants) are decreased in dose, changed to a short acting product, and/or discontinued.
3. Enforcement of good sleep hygiene is documented.
4. All medical, neurological, and psychiatric disease states causing chronic insomnia are being adequately treated with appropriate medication at therapeutic doses.
5. Patient has a documented trial and therapy failure with zaleplon.

Proposed Prior Authorization Criteria (*changes italicized*)

Preferred agents are available without prior authorization (PA). *Requests for doses above the manufacturer recommended dose will not be considered.* Prior authorization is required for all non-preferred non-benzodiazepine sedative/hypnotics. Payment for non-preferred non-benzodiazepine sedative/hypnotics will be authorized only for cases in which there is documentation of previous trials and therapy failures with, *at a minimum, three (3) preferred agents.* Payment for non-preferred non-benzodiazepine sedative/hypnotics will be considered when the following criteria are met:

1. A diagnosis of insomnia; *and*
2. Medications with a side effect of insomnia (i.e. stimulants) are decreased in dose, changed to a short acting product, and/or discontinued; *and*
3. Enforcement of good sleep hygiene is documented; *and*
4. All medical, neurological, and psychiatric disease states causing chronic insomnia are being adequately treated with appropriate medication at therapeutic doses.
5. *In addition to the above criteria, requests for suvorexant (Belsomra) will require documentation of a trial and therapy failure with at least one non-preferred agent, other than suvorexant, prior to consideration of coverage.*
6. *Non-preferred alternative delivery systems will only be considered for cases in which the use of the alternative delivery system is medically necessary and there is a previous trial and therapy failure with a preferred alternative delivery system if available.*

The required trials may be overridden when documented evidence is provided that use of these agents would be medically contraindicated.

Prior to the formal recommendation of clinical prior authorization criteria going to the Department of Human Services, the DUR Commission is interested in the opinions of the members of your organization. Any comments regarding the proposed prior authorization criteria may be forwarded to me and will be shared with the DUR Commission members. My contact information is listed below. Please have comments/feedback submitted to me on or before May 1, 2015.

Sincerely,

A handwritten signature in black ink that reads "Paula Smith R.Ph." The signature is written in a cursive style.

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