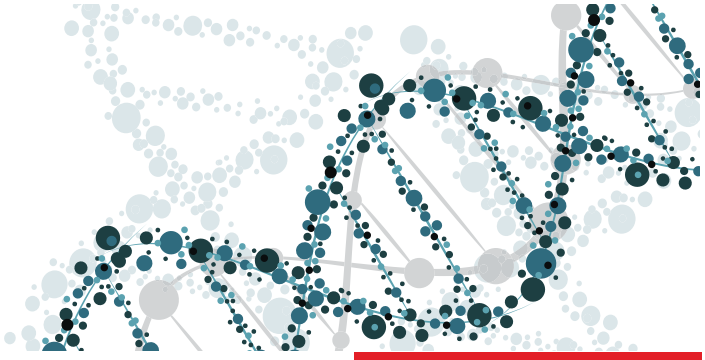
RGA

Global Health Brief



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Experimental Treatments – Current Considerations

At a time of continuous and rapid medical advances, insurers need to be sure that the treatments they are being asked to cover are medically appropriate and do not fall under the common policy exclusion of "experimental treatment."

Many health insurers exclude experimental treatments without clearly defining which treatments they would consider experimental. In this Global Health Brief, we discuss the need for clear definitions in policy language. We also explore how drugs, treatments, and devices are developed, licenced, and become adopted as the accepted standard of care, and provide guidance on what is truly experimental and when it may be appropriate to consider making exceptions.

Sincerely,

Colin Weston
Vice President, Head of Global Health Claims
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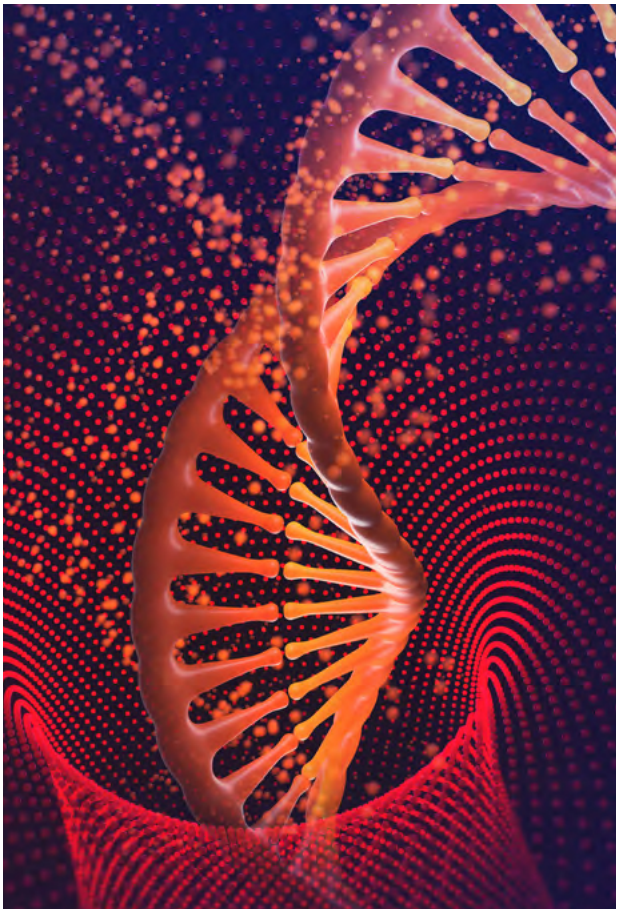
Experimentation, invention, and improvements in medical science are expected and essential to improving quality of life and advancing life expectancy. However, health insurance, which is designed and priced to cover the cost of proven treatments, does not cover those deemed experimental.

Except where required by law or regulation, health insurers should not cover experimental or unproven treatments due to the following risks:

- The effectiveness of these treatments, and whether they can facilitate diagnosis, relief, or cure, is unknown
- Costs will be ill-defined, and claimants may, in addition to the unproven/experimental treatment, also require covered drugs and therapies of standard clinical protocols for their conditions, which could lead to higher claims costs
- Possible side effects of the treatments
- Any insurer providing cover could be seen as endorsing such treatments, which might result in harm to a claimant

To ensure customers are treated fairly, insurers should incorporate appropriate wording, including a clear definition and exclusion, into their policy documents, to clarify for insured persons, treating physicians, and claims assessors what is and is not covered.



Sample policy exclusion language and supporting definitions

This Policy does not cover the cost of Experimental Treatment or Experimental Drugs.

"Experimental Treatment" shall mean treatment that has either:

- not been recognized as established by an appropriate regulatory body

or

- has not undergone a structured clinical trial and assessment with sufficient peer-reviewed evidence published in medical journals to confirm effectiveness which has been incorporated into clinical guidelines and pathways issued by appropriate bodies such as medical colleges, societies, or associations.

"Experimental drugs" shall mean:

- drugs not licenced by the FDA, EMA, or other such regulatory authority recognized in the country in which the drug is received,

or

- drugs licenced by an appropriate authority as described in the prior bullet point, but
    - not used either in accordance with their license or as recommended by an appropriate expert body in accordance with a clinical protocol or pathway for the condition for which the drug is being prescribed

Treatment Development and Licensing

New drugs are developed in a lengthy and costly multi-step process, which encompasses pre-clinical research and a four-phase clinical trial process that ultimately leads to licensing.

Drugs in Phase I, II, or III trials are being tested on humans to determine efficacy, dosage, and side effects. These are normally considered experimental and are not covered. Drugs receive a marketing license following the successful completion of Phase III trials and a review of results by licensing authorities. As drugs become adopted, clinical guidelines are developed and issued based on ongoing reviews and analyses of evidence.

Once licensed, if the approved drug is used in accordance with the license's terms, the drug should not be considered experimental. Following licensing, drugs enter Phase IV trials, which monitors licensed drugs to determine long-term benefits, risks, and side effects. Drugs in Phase IV trials should also not be considered experimental.

Since pharmaceutical companies or research foundations generally cover the costs of clinical trials for drugs under development, there should be no need for insurers to provide indemnity for trial participants. However, if an insurer wishes to develop a benefit to cover expenses related to clinical trials, this could take the form of a fixed lump sum for participation in a Phase III trial or reimbursement of ancillary costs such as travel and accommodation expenses.

Medical devices are subject to a similar phased testing and licensing process as that of drugs.

When evaluating a claim involving a medical device, claims assessors should confirm that that the machine or device is licenced and is being used for its licensed purpose. Assessors should also be alert for claims where the device is itself licensed, but the actual procedure or treatment being provided via the device is still experimental.

On-Label and Off-Label Use

On-label drugs are those prescribed and used in accordance with their license. If a drug is used not in accordance with its license it is considered "off label."

Off-label drugs can be classified in two ways:

- "Off-label on-guideline" use is when the drug is not prescribed for a condition for which it has been licensed but for a use which has been peer-reviewed for efficacy and recommended by recognized guideline-issuing organizations (such as the National Cancer Comprehensive Network [NCCN], the European Society for Medical Oncology [ESMO], or a specialty medical college or society). RGA recommends that off-label on-guideline use not be classified as experimental by health insurers.
- "Off-label off-guideline" use is when a drug prescribed is for a use for which it is not licensed and where said use has not been incorporated into an appropriate clinical guideline such as that described above. These drugs are classed as experimental and should not be covered.

There may be occasions when insurers are asked to cover the cost of drugs or medical devices that are off-label off-guideline or where studies on potential treatment indications are still in Phase I, II, or III clinical trials and therefore classified as experimental. In these cases, an insurer may wish to consider paying a portion of the claim if the treatment is part of a specific clinical trial by an appropriate governing or regulatory body within a controlled framework or is part of a strictly monitored compassionate use or expanded access program for patients with a life-threatening condition who lack further treatment options. Since such drugs are considered experimental, all contributions towards costs should be paid on an ex-gratia basis and, if appropriate, with the concurrence of the insurer's reinsurer.

In the event of a public health emergency, an emergency use authorization (EUA) for a specific drug or treatment (e.g., a vaccine) may be granted by authorities such as the FDA or EMA. despite the drug or treatment not yet being out of clinical trials. During the EUA period, claims for the drug or treatment should be processed as if on-label and not experimental.

Non-Pharmacological Therapies and Techniques

Innovation in non-pharmacological therapies and surgical techniques is continuous and key to improving patient outcomes. However, unlike drugs and devices, recognition of novel therapies and techniques are not subject to the same governance and review required to license new drugs and devices.

In addition, recognition of new treatments as "standard of care" is usually condition-specific and are adopted by specialists in the same clinical field and/or approved by a hospital's ethics committee, based either on outcomes of clinical trials or sufficient evidence of treatment results.

When determining if a new non-pharmacological treatment is experimental, insurers may not be able to rely on the authorization of a regulatory body. They may need to make their own assessments and determinations, and so should use consistent assessment criteria.

Insurers should also be willing to consider additional evidence to substantiate appropriate use of an experimental treatment but should continue to apply available established guidelines.

Sample policy language for assessment criteria

To NOT be classed as experimental, a claimed treatment must either have received final approval from an appropriate government or regulatory body, or all of the following criteria must be met:

- There is sufficient scientific evidence to draw conclusions about the treatment's effect on patient health outcomes
- It must be shown to improve net health outcomes
- It must be shown to be as beneficial as any established alternative
- Health outcomes must be consistent and repeatable
- Improvement attributable to the treatment must be attainable in non-investigational settings

Occasions when an insurer may wish to consider cover for Experimental Treatment:

- If required to by law or regulation: Local laws or insurance regulations may mandate what treatments insurers are allowed to cover or exclude. For example, the U.S. Affordable Care Act requires insurers to cover costs associated with any portion of a clinical trial that falls under a standard treatment protocol. This would include drugs as well as associated laboratory or radiological tests generally associated with care.
- If used as a replacement for an established treatment: An insurer may wish to contribute the amount it would have paid towards the cost of the conventional covered treatment, with the understanding that the claimant cannot then revert to the standard treatment protocol.
- Based on clinical outcome: An insurer may agree with a care provider to cover an experimental treatment based on a successful outcome. In such an arrangement, criteria for success would need to be defined up front. The insure would cover the cost of treatment but would receive a rebate from the provider if the pre-agreed success criteria were not achieved.
- Compassionate grounds: An insurer may also, via a strict pre-authorization process, cover certain experimental treatments on compassionate grounds. Such grounds may include a patient suffering a serious or immediately life-threatening condition for which there are no comparable or satisfactory alternative therapies to treat or diagnose the condition.

There may also be circumstances where a treatment, or a course of treatment, may not strictly adhere to guidelines but may be appropriate for certain patients based on their diagnoses and comorbidities. An insurer may want to employ the services of external experts to assess such cases if the expertise needed to assess the situation is not available internally.

If a novel treatment is proven to be effective but is more expensive, an insurer should not rely on the experimental treatment exclusion but instead should look to limit reimbursement based on policy wording pertaining to reasonable and customary costs, which should ideally preclude treatment that is more expensive than an equally effective treatment.

All payments outside of policy terms and conditions should be made ex-gratia, so as not to set precedent or prejudice the insurer's use of policy terms in the future.

Reinsurance Considerations

If an insurer is considering paying for an experimental treatment that would be outside of the terms and conditions of the insurer's policy, the insurer should, if required by their reinsurance arrangement, seek reinsurance support in advance of making payment.

Summary

- "On-Label" drug use is not experimental, even if the drug is new and expensive
- "Off-Label On-Guideline" drug use is not experimental
- "Off-Label Off-Guideline" drug use is experimental, and claims should be subject to experimental treatment exclusions
- Non-pharmacological treatment, therapies, or techniques are not experimental if they have undergone appropriate studies, there is sufficient peer reviewed evidence, and they are part of clinical guidelines/pathways from an appropriate body

It is not appropriate for insurers to reimburse claims based on the concept that "the treating doctor knows best" or "because the treating doctor says so." Treatment should be provided in accordance with best practice guidelines, and if subject to a challenge, insurers should seek to establish if there are any unique circumstances in relation to the claimant that justify deviation from best practice. ■