



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all health benefit plans administered by CIGNA Companies including plans formerly administered by Great-West Healthcare, which is now a part of CIGNA.

**Subject Partial Left Ventriculectomy,
Dynamic Cardiomyoplasty and
Ventricular Reshaping in the
Treatment of Heart Failure**

**Effective Date 3/15/2011
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Biventricular Pacing/Cardiac
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Total Artificial Heart
Ventricular Assist Devices (VADs)

INSTRUCTIONS FOR USE

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Coverage Policy

CIGNA does not cover ANY of the following procedures/devices for the treatment of heart failure because each is considered experimental, investigational or unproven:

- partial left ventriculectomy
- dynamic cardiomyoplasty
- surgical ventricular restoration
- Acorn CorCap™ Cardiac Support Device (CSD)

General Background

Heart failure can develop from any condition that overloads, damages, or reduces the efficiency of the heart muscle, impairing the ability of the ventricles to fill with or eject blood. Heart muscle may be damaged by myocardial infarction, coronary artery disease, infection, toxic chemical exposure, or years of untreated hypertension or heart valve abnormality. Treatment of heart failure includes pharmacologic interventions, including diuretics, angiotensin-converting enzyme inhibitors, vasodilators, digitalis, and beta-blockers. Pharmacologic therapy is ineffective in approximately 40% of heart failure patients, however. Heart transplantation is the most effective treatment for advanced heart failure, with most transplant centers achieving one-year survival rates of 85% or greater. Most transplant recipients can expect a ten-year survival of

approximately 50%. The demand for donor hearts far exceeds the available supply, however. Several surgical approaches have been explored as alternative treatments for patients with end-stage heart failure (ECRI, 2008).

Partial Left Ventriculectomy

Partial left ventriculectomy (PLV), also referred to as the Batista procedure, was introduced in 1994 by Brazilian cardiac surgeon Randas Batista to treat patients with dilated cardiomyopathy and was first performed in the United States in 1995. The procedure was developed to reduce the size and reshape the heart in order to improve mechanical function. Batista theorized that resecting a viable section of the lateral left ventricular (LV) wall would reduce LV diameter and, consequently, LV wall stress in patients with dilated cardiomyopathy. The procedure consists of resecting the left ventricle between both papillary muscles from the apex to the mitral annulus. The procedure is usually done in conjunction with mitral valve annuloplasty or replacement, although it is sometimes performed alone. Early results of PLV in uncontrolled trials were positive, with reports of improved symptoms of heart failure and improvements in quality of life for patients who survived the perioperative period. Although short-term results were promising, long-term positive outcomes have not been demonstrated. Numerous complications of PLV have been reported, including sudden death, progressive postoperative heart failure, recurrent arrhythmias, bleeding, renal failure, respiratory failure, and infection. Perioperative mortality rates in published studies range from 3–30% for elective PLV. Mortality rates reported for emergency PLV in patients who were in poor condition, however, were much higher, ranging from 50–87%.

Suma et al. (2007) evaluated surgical ventricular restoration with mitral reconstruction in the treatment of patients with advanced heart failure due to idiopathic dilated cardiomyopathy. Of 95 patients treated, 44 were in NYHA Class III, 51 were in NYHA Class IV, and 33 patients were inotropic dependent. All patients underwent left ventriculoplasty (septal anterior ventricular exclusion in 38, partial left ventriculectomy in 57) and mitral reconstruction (repair in 53 patients, replacement in 42). Hospital mortality was 11.6% (11 of 95), with 6.6% (5 of 76) deaths occurring in elective procedures, and 31.6% (6 of 19) in emergency procedures. The ejection fraction and cardiac index increased from $22.3 \pm 6.3\%$ to $27.2 \pm 8.0\%$, and from $2.3 \pm 0.5 \text{ ml/m}^2/\text{min}$ to $2.8 \pm 0.5 \text{ ml/m}^2/\text{min}$, respectively ($p < 0.001$). Late death occurred in 27 cases, and 22 of these were cardiac deaths. The mean NYHA Class among survivors was 1.7. One-, three-, and five-year survival rates were 72.8%, 61.4%, and 50.5%. Preoperative inotropes as well as advanced age were significant predictors of postoperative mortality. The authors acknowledged that it is difficult to demonstrate the isolated effect of each procedure on ventricular function.

An international registry of PLV was begun in 1997 and has been updated periodically. The Fourth International Registry Report, published in 2005, was updated and expanded to include 568 cases voluntarily reported from 52 hospitals in 12 countries. The report concluded that avoidance of risk factors appears to have contributed to recent improvements in survival, and may help stratify patients for left ventricular volume reduction. Risk factors were identified as poor preoperative patient condition, such as NYHA Class IV; depressed contractility and decompensation that required an emergency procedure; early surgery date; lack of experience; dilated cardiomyopathy as the underlying pathology; and extended myocardial resection. The report stated that the procedure has been largely abandoned, except in Asia, where experienced centers continue to perform the procedure in patients in better condition with preserved myocardial contractility.

In a prospective observational study at the Cleveland Clinic, 59 patients with cardiomyopathy and advanced heart failure underwent PLV with mitral valve surgery. Early follow-up showed an improvement in functional class in patients who survived, and short-term survival of 63–82%. Although some patients improved clinically, no physiologic basis for clinical improvement was apparent. Echocardiographic measurements remained abnormal, and very little improvement in hemodynamics was seen. The authors stated that cardiac transplant will normalize hemodynamics and ejection fraction, and it is well established that the prognosis in patients with heart failure is tied to structural, hemodynamic and neurohormonal variables, including norepinephrine, atrial natriuretic peptide and TNF-alpha. The absence of sustained benefit following PLV is understandable, since the procedure does not produce this normalization of measurable parameters. Short-term clinical improvement could be related to optimal medical therapy and the close medical follow-up provided in a heart failure clinic. The authors concluded that PLV can provide structural remodeling of the heart with temporary clinical improvement, but perioperative failures and the return of heart failure limit the propriety of the procedure (Starling, et al., 2000).

Guidance from the National Institute for Clinical Excellence (NICE) (United Kingdom) published in 2004 concluded that safety and efficacy of PLV does not appear adequate for this procedure to be performed without special arrangements for consent and for audit or research.

There is insufficient evidence in the published medical literature to demonstrate the safety and efficacy of PLV (Batista procedure) in the treatment of end-stage heart failure with cardiomyopathy. Major complications such as sudden death, postoperative heart failure and arrhythmias result in high morbidity and mortality. Event-free survival is poor (37% at two years), and, because published trials were not randomized, there is no evidence that PLV results in improved outcomes as compared to currently available medical and surgical treatment. Patient selection criteria have not been defined. Short-term clinical improvement may occur in some cases, but no physiologic basis for this temporary improvement has been demonstrated, and it is likely related to optimal medical therapy and the close medical follow-up provided. No improvement has been demonstrated in measurable indicators of heart failure, such as hemodynamics, ejection fraction, echocardiographic measurements, neurohormonal variables and New York Heart Association (NYHA) functional class.

Dynamic Cardiomyoplasty

Dynamic cardiomyoplasty was first reported in 1985 and has been investigated as either a bridge to, or an alternative to, transplantation for patients with end-stage heart failure. Dynamic cardiomyoplasty is a surgical procedure in which a latissimus dorsi muscle flap is transposed into the chest and wrapped around the ventricles of the failing heart. This skeletal muscle flap is then electrically stimulated to contract in synchrony with ventricular systole. Over time, pacing of the skeletal muscle may produce morphologic, molecular and functional changes in the skeletal muscle, including notable reduction in muscle fatigue with repeated stimulation. Researchers have proposed that the muscle wrap may provide an external constraint that reduces progressive ventricular dilatation and remodeling, improves systolic ejection by the stiffening and shortening of the muscle, and decreases wall tension in the ventricle by increasing effective muscle wall thickness (Vitali, et al., 2003). Complications of dynamic cardiomyoplasty include sudden death, progressive heart failure, multi-organ failure, infection and arrhythmias.

Furnaby et al. (1996) conducted a multicenter nonrandomized study to assess the effect of dynamic cardiomyoplasty in 68 patients with chronic heart failure. Patients were eligible if they had heart failure due to dilated cardiomyopathy or ischemic heart disease and had not improved despite optimal drug therapy; were in NYHA functional class III; and fell within specified parameters for ejection fraction and pulmonary capillary wedge pressure. Each center also enrolled nonrandomized, medically treated reference patients. The in-hospital mortality rate was 12% (8 of 68 patients); the six-month survival rate was 75% (\pm 5%); and the twelve-month survival rate was 68% (\pm 5%). Slight improvements in symptoms were reported at six months, but no significant change was seen in peak oxygen consumption, cardiac index or pulmonary capillary wedge pressure. There was no significant difference in survival between the treatment and reference groups at any point during the 12-month evaluation period. The authors concluded that dynamic cardiomyoplasty improves ventricular systolic function, reduces symptoms of heart failure and improves objective measures of quality of life in patients with congestive heart failure. The improvements cited, however, were modest and were actually lower than typical improvements noted during the same period of time (mid-1990s) for pharmacologic interventions. In addition, clear conclusions about the treatment arm results cannot be made because there was no type of placebo treatment or medication in the reference group. Other studies have demonstrated that placebo treatment alone can produce improvement in clinical status, NYHA functional classification and exercise capacity in patients with heart failure. The lack of placebo treatment prevents a meaningful comparison of outcomes between the treatment and reference groups.

The Furnaby trial described above is the only completed multicenter trial of dynamic cardiomyoplasty. This trial included only patients in NYHA functional class III. These patients can often be effectively managed and rehabilitated by experienced cardiologists and heart failure specialists. Dynamic cardiomyoplasty is considered too risky for patients in advanced heart failure, especially those on inotropic or intra-aortic balloon pump support. Dynamic cardiomyoplasty has been largely abandoned by the surgical community because of the complexity of the procedure, the high operative morbidity and mortality, and disappointing long-term results. The promising outcomes reported in early, uncontrolled experiences have not been substantiated in well-designed clinical trials. Insufficient data have been reported in the published medical literature to support the safety and efficacy of dynamic cardiomyoplasty.

Surgical Ventricular Restoration

Surgical ventricular restoration (SVR), also referred to as left ventricular reconstruction, endoventricular circular patch plasty, or the Dor procedure, has been explored as a treatment for patients with ischemic cardiomyopathy. Several techniques and devices are used for SVR, and numerous patches have received U.S. Food and Drug Administration (FDA) approval. The procedure has been performed on patients post-infarction with large anterior wall akinetic or dyskinetic segments and a spherically dilated left ventricle. With the patient on a heart-lung machine, an incision is made into the left ventricle to exclude but not remove the damaged area, and the heart is opened. In most cases a balloon or plastic model is temporarily inserted to serve as a template to ensure that the reconstructed ventricle is of the appropriate size and shape for the patient. The heart wall is then stretched around the device. The opening is closed with sutures and/or a patch. Left ventricular function is reportedly improved by removing non-contractile antero-lateral segments, reducing the diameter and restoring the shape of the left ventricle. The procedure is performed in conjunction with coronary revascularization and mitral valve repair, if necessary (Di Donato, et al., 2001; Dor, 2004).

The Surgical Treatment for Ischemic Heart Failure (STICH) trial, a multicenter, non-blinded, randomized trial at 127 sites in 26 counties (n=1000), was designed to define the role of cardiac surgery in the treatment of heart failure and coronary artery disease. One of the major hypotheses of the trial (Hypothesis 2) was that surgical ventricular reconstruction, when added to coronary artery bypass graft (CABG), would decrease the rate of death or hospitalization for a cardiac event, compared to CABG alone. Between 2002 and 2006, patients with an ejection fraction of 35% or less, coronary artery disease amenable to CABG, and dominant anterior left ventricular dysfunction suitable for surgical ventricular reconstruction were randomly assigned to either CABG alone (n=499) or to CABG with surgical ventricular reconstruction (n=501). The end-systolic volume index was reduced by 19% in the surgical ventricular reconstruction group, compared to a reduction of 6% in the CABG-alone group. Improvements in cardiac symptoms and exercise tolerance were similar in both groups. There was no significant difference between the two groups in the primary outcome measure, a composite of death from any cause and hospitalization for cardiac causes, which occurred in 292 patients (59%) in the CABG group, and 289 patients (58%) in the CABG plus surgical ventricular restoration group (Jones et al., for the STICH Hypothesis 2 Investigators, 2009).

Menicanti et al. (2007) reported operative and long-term mortality in an observational study of 1161 consecutive patients treated for heart failure and/or angina with surgical ventricular restoration, with or without CABG, and with or without mitral repair/replacement. A complete echocardiogram was performed in 488 patients (study group). Thirty-day cardiac mortality was 4.7% (55/1161) overall and 4.9% (24/488) in the study group. Hospital mortality was associated with mitral regurgitation, NYHA Class greater than II, and diastolic dysfunction. Global systolic function improved postoperatively; ejection fraction improved from $33\% \pm 9\%$ to $40\% \pm 10\%$ ($p < .001$); end-diastolic and end-systolic volumes decreased from 211 ± 73 to 142 ± 50 and 145 ± 64 to 88 ± 40 ml, respectively ($p < .001$) early after surgery. NYHA functional class improved from 2.7 ± 0.9 to 1.6 ± 0.7 ($p < .001$) late after surgery. Long-term survival in the overall population was 63% at 120 months. The authors acknowledged the following limitations of this study: the collection of data was not uniform, and was prospective in a minority of the population; the severity of heart failure was based on NYHA functional class, which has limitations, and the quality of life, critical in this type of patient with severe heart failure, was not estimated.

The Reconstructive Endoventricular Surgery returning Torsion Original Radius Elliptical shape to the left ventricle (RESTORE) study was conducted to determine how surgical ventricular restoration affects early and late survival in a registry of 1198 post-anterior infarction congestive heart failure patients treated by the international RESTORE team. The most recent RESTORE data was published by Athanasuleas et al. (2004). Concomitant procedures included CABG (95%), mitral valve repair (22%), and mitral valve replacement (1%). Overall 30-day mortality after SVR was 5.3% (8.7% with mitral repair vs. 4.0% without repair). Ejection fraction increased from $29.6 \pm 11.0\%$ preoperatively to $39.5\% \pm 12.3\%$ postoperatively. The left ventricular end-systolic volume index decreased significantly. Advanced NYHA functional class and age ≥ 75 years were seen as risk factors for death. Five-year freedom from hospital readmission for heart failure was 78%. Preoperatively, 67% of patients were NYHA class III or IV and postoperatively, 85% were class I or II.

Early published results of Dor's single-center experience with the procedure demonstrated early and late improvement in NYHA functional class and ejection fraction. Comparable results were seen in the Surgical Anterior Ventricular Endocardial Restoration (SAVER) trial, a multicenter trial by an international group in 11 centers (Athanasuleas, et al., 2001). The SAVER trial evaluated the safety and efficacy of the procedure in 439 patients who also underwent concomitant coronary artery bypass grafting (CABG), mitral valve repair and mitral valve replacement. Postoperatively, ejection fraction increased from 29 ± 10.4 to 39 ± 12.4 , and left ventricular

end systolic volume index decreased from 109 ± 71 to 69 ± 42 ml/m². Survival at 18 months was 89.2%, and freedom from hospital readmission for heart failure was 85%.

Additional retrospective studies have compared CABG plus ventricular restoration to CABG alone (Cotrufo et al., 2005) and have also compared ventricular restoration to heart transplantation (Maxey et al., 2004). Published evidence on the safety and efficacy of SVR consists largely of case series and retrospective studies. Controlled studies are needed to determine whether a decrease in ventricular size results in diastolic compromise; whether an ejection fraction increase in a smaller ventricle results in an increased stroke volume; and whether remodeling after SVR compromises long-term success. The safety and efficacy of SVR or the benefit of this procedure as compared to standard treatment options for heart failure, including drug therapy and coronary revascularization (i.e., CABG or angioplasty and stenting), has not been demonstrated in the published medical literature.

Acorn CorCap™ Cardiac Support Device

The Acorn CorCap Cardiac Support Device (CSD) (Acorn Cardiovascular, St. Paul, MN) is designed to treat heart failure by constraining the heart to prevent further dilation. It is constructed of a patented, knitted polyester fabric similar to the fabric in vascular grafts, and is designed to optimize circumferential support and minimize fibrosis. The CorCap CSD, which has been described as a biocompatible support jacket, is positioned around the ventricles and sutured posteriorly and laterally slightly above or below the atrial-ventricular groove. It is adjusted to fit snugly and cause an immediate slight reduction in heart circumference. The Acorn CorCap CSD has not received FDA approval and is limited to investigational use in the United States.

Rubino et al. (2009) conducted a comparative study to evaluate the early differences in neurohormonal release and echocardiographic findings after CorCap and mitral annuloplasty in patients with congestive heart failure secondary to dilated cardiomyopathy and functional mitral regurgitation (FMR). A total of 30 consecutive patients with FMR who were eligible for restrictive mitral annuloplasty (RMA) were randomized to RMA alone or RMA and cardiac restraint with the CorCap Cardiac Support Device. The mean follow-up was 11.8 ± 4.0 months in the RMA group and 12.1 ± 3.8 months in the CorCap group. Echocardiography showed a trend toward a slightly better functional improvement in the CorCap plus RMA group. Both groups showed improved results for SF-36, New York Heart Association (NYHA), and N-terminal pro-B-type natriuretic peptide (NT-proBNP). Although the CorCap plus RMA group had better SF-36 and NYHA scores at discharge, results were comparable between the two groups at follow-up. Both groups showed reduced NT-proBNP levels during the course of the study, with lower scores recorded in the CorCap group. There was no difference between the groups in survival, freedom from congestive heart failure, or freedom from rehospitalization.

The Acorn Clinical Trial, conducted at 29 centers in the United States and Canada, was designed to evaluate the safety and efficacy of the CorCap CSD in 300 patients with heart failure who were receiving optimal medical therapy. Patients with significant mitral regurgitation, and a clinical indication for mitral valve replacement (MVR), were enrolled in the MVR group (n=193), and were randomized to treatment with MVR surgery along with CSD (treatment group), or to MVR surgery alone (control group). Patients without an indication for MVR surgery (n=107) were randomized to medical therapy with CSD (treatment group), or medical therapy alone (control). Eligible patients had NYHA Class III-IV heart failure, an LVEF of 35% or less, LV end diastolic dimension of 60 mm or greater, or an LV end-diastolic dimension index 30 mm/m². The median duration of follow-up was 22.9 months (range 12–48). In terms of vital status, 38% of treatment patients were considered improved compared to 27% of control patients, and 37% of treatment patients were considered worsened, compared to 45% of control patients. There was a significant reduction in major cardiac procedures in the treatment group (21 procedures in 19 patients) compared to the control group (48 procedures in 33 patients) (p=0.01). There was no difference in survival between the treatment and control groups (p=0.85). More patients in the treatment group improved by at least one NYHA class (45%) than in the control group (33%). Limitations of the trial include the lack of blinding, and the fact that 174 patients had to have baseline NYHA class imputed because the NYHA Core Lab was implemented after trial enrollment. The authors noted two issues that may be important for the clinical application of the CorCap; implantation of the mesh support will result in adhesions that may complicate subsequent cardiac surgery, and although there has been no clinical evidence of pericardial constriction in routine surveillance echocardiograms, this cannot be excluded as a rare and late complication (Mann et al., 2007).

Starling et al. (2007) conducted further analysis of the Acorn trial to evaluate the impact of the CorCap device on left ventricular remodeling. Echocardiograms were obtained every six months until the last patient was followed

for one year, then annually thereafter. Standard measurements of LV volumes, ejection fraction and sphericity index were made in a blinded fashion by Core Lab at the Mayo Clinic. Patients treated with the CorCap CSD had significant reductions in LV end diastolic volume (average difference 18.8 ml; p=0.005), and LV end systolic volume (average difference 15.6 ml; p=0.013), compared to the control group. Sphericity index was increased significantly in the treatment group (average difference 0.045 units; p=0.018), and these changes were maintained over three years of follow-up. These changes were observed whether the device was implanted with or without mitral valve surgery.

Acker et al. (2006) evaluated the safety and efficacy of mitral valve surgery with and without the CorCap device in the subgroup of patients enrolled in the Acorn Clinical Trial who required mitral valve repair or replacement. The 30-day operative mortality rate was 1.6% at 30 days. Mitral surgery was associated with reverse remodeling, as evidenced by progressive reductions in LV end-diastolic and systolic volume and LV mass, as well as increases in LV ejection fraction and sphericity index. The authors reported that the addition of the CorCap CSD led to greater decreases in LV end-diastolic volumes and LV end-systolic volume, a more elliptical shape, a trend toward a reduction in major cardiac procedures, and improvement in quality of life, compared to mitral surgery alone.

The safety and efficacy of the Acorn CorCap CSD have not yet been established in the published medical literature, and, as stated above, the device has not received U.S. Food and Drug Administration (FDA) approval.

Professional Societies/Organizations

The ACC/AHA (American College of Cardiology/American Heart Association) Guideline Update for the Management of Chronic Heart Failure in the Adult (Hunt et al., 2005) classifies recommendations as Class I, Class IIa, Class IIb, and Class III. The classification system is described as follows:

- Class I: Benefit >>>Risk; Procedure/Treatment should be performed/administered
- Class IIa: Benefit >> Risk; Additional studies with focused objectives needed. It is reasonable to perform procedure/administer treatment
- Class IIb: Benefit \geq Risk; Additional studies with broad objectives needed; additional registry data would be helpful. Procedure/treatment may be considered.
- Class III: Risk \geq Benefit; Procedure/treatment should not be performed/administered, since it is not helpful and may be harmful.

The ACC guideline includes the following as a Class III recommendation:

- Partial left ventriculectomy is not recommended in patients with nonischemic cardiomyopathy and refractory end-stage heart failure.

The guideline states that, although both cardiomyoplasty and left ventriculectomy generated considerable excitement as potential surgical approaches to the treatment of refractory heart failure, these procedures failed to result in clinical improvement and were associated with a high risk of death.

Surgical ventricular restoration is mentioned as one of several surgical approaches that have emerged as potentially beneficial in patients with ischemic heart failure, and the guidelines state that the goals of these procedures generally include revascularization, reduction in mitral regurgitation, and restoration of a more normal geometry and function of the left ventricle. The ACC/AHA guideline also states that there is developing experience with surgical devices that are designed to alter physical stresses on the left ventricle, and clinical trials are underway in Europe and the United States to evaluate these devices.

Summary

Treatment options for heart failure include both medical and surgical treatment, including ventricular assist devices (VADs), resynchronization therapy, coronary revascularization (i.e., coronary artery bypass graft or angioplasty and stenting), valve repair or replacement, total artificial heart, and heart transplantation. Heart transplantation is the definitive treatment for eligible patients, but the supply of donor hearts has decreased, while the demand has increased significantly. The surgical interventions described above have emerged in an effort to treat patients with heart failure refractory to optimal medical and/or surgical management. There is insufficient evidence in the published medical literature, however, to demonstrate the safety and efficacy of

partial left ventriculectomy (PLV), dynamic cardiomyoplasty, surgical ventricular restoration (SVR), or the Acorn CorCap Cardiac Support Device (CSD).

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Experimental/Investigational/Unproven/Not Covered:

33548	Surgical ventricular restoration procedure, includes prosthetic patch, when performed (e.g., ventricular remodeling, SVR, Saver, DOR procedure)
33999 [†]	Unlisted procedure, cardiac surgery

[†]**Note:** Experimental, investigational or unproven and not covered when used to report the procedures addressed in this Coverage Policy.

ICD-9-CM Diagnosis Codes	Description
411.1	Intermediate coronary syndrome
411.81	Acute coronary occlusion without myocardial infarction
411.89	Other acute and subacute form of ischemic heart disease
414.00-414.19	Other forms of chronic ischemic heart disease
414.8	Other specified forms of chronic ischemic heart disease
414.9	Unspecified chronic ischemic heart disease
425.4	Other primary cardiomyopathies
428.0-428.9	Heart failure

*Current Procedural Terminology (CPT®) ©2010 American Medical Association: Chicago, IL.

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Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	03/15/2008	0312	Partial Left Ventriculectomy, Dynamic Cardiomyoplasty and Ventricular Reshaping in the Treatment of Heart Failure

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